

# **EXHIBIT 14**

David Bliesner, Ph.D.

Videotaped

January 25, 2011

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IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION

MDL NO: 1968

IN RE: DIGITEK PRODUCT LIABILITY  
LITIGATION,

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100 N. Tampa Street  
Suite 2900  
Tampa, FL 33602  
January 25, 2011  
at 9:08 a.m.

VIDEOTAPE DEPOSITION OF DAVID BLIESNER, Ph.D.

Taken on behalf of the Defendants before  
PHILIP RYAN, RPR, Court Reporter, Notary Public  
in and for the State of Florida at Large,  
pursuant to Defendant's Notice of Taking  
Deposition in the above cause.



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1 APPEARANCES:

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16 Attorney for Defendant Actavis Totowa,  
LLC, Actavis, Inc.,  
17 and Actavis Elizabeth, LLC

18 ALICIA J. DONAHUE, ESQUIRE  
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21 Attorney for Mylan Pharmaceuticals,  
22 Inc., Mylan Inc., Mylan Bertek  
Pharmaceuticals, Inc., and UDL Labs

23 ALSO PRESENT:

24 Alan Pokotilow, videographer

25

David Bliesner, Ph.D.

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DIRECT EXAMINATION:

BY MR. MORIARTY

5

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BY MS. DONAHUE

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Exhibit 106 Notice of taking video deposition 226  
duces tecum.

9

Exhibit 107 Handwritten notes, re Mylan 45  
deposition exhibits.

10

Exhibit 108 Handwritten notes re. Plaintiffs' 45  
Exhibits 1 to 263.

11

Exhibit 109 Handwritten notes taken during the 240  
deposition.

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1 THE VIDEOGRAPHER: My name is Alan 09:08

2 Pokotilow with Veritext. The date today is 09:08

3 January 25 of 2011. The time is 09:08

4 approximately 9:08 a.m. 09:08

5 This deposition is being held at the 09:08

6 office of Shook, Hardy & Bacon, located at 100 09:08

7 North Tampa in Tampa, Florida. 09:08

8 The caption of the case is in regards to 09:08

9 Digitek product liability litigation, MDL 09:08

10 number 168, to be heard in United States 09:08

11 District Court of the Southern District of 09:08

12 West Virginia, Charleston Division. 09:08

13 The name of the witness is Dr. David 09:08

14 Bliesner. 09:08

15 At this time the attorneys will please 09:08

16 identify themselves and the parties they 09:08

17 represent, after which then our court reporter 09:08

18 Phil Ryan of Veritext will swear the witness 09:08

19 and we can proceed. 09:08

20 MR. MORIARTY: My name is Matt 09:09

21 Moriarty, and I represent the Actavis 09:09

22 Defendants. 09:09

23 MR. ANDERTON: Michael Anderton also on 09:09

24 behalf of the Actavis defendants. 09:09

25 MS. DONAHUE: Alicia Donahue, Shook 09:09

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1 Hardy & Bacon on behalf of the Mylan 09:09

2 Defendants and UDL Laboratories. 09:09

3 MR. KERENSKY: And for the Plaintiffs 09:09

4 we have Mike Kerensky, Terry Fitzpatrick, 09:09

5 and Meghan Johnson Carter. 09:09

6 THE VIDEOGRAPHER: Would the court 09:09

7 reporter please swear the witness. 09:09

8 The Deponent herein, 09:09

9 DAVID BLIESNER, Ph.D., 09:09

10 being first duly sworn to tell the truth, the 09:09

11 whole truth, and nothing but the truth, was 09:09

12 examined and testified as follows: 09:09

13 DIRECT EXAMINATION 09:09

14 BY MR. MORIARTY: 09:09

15 Q. Tell us your name. 09:09

16 A. David Bliesner. 09:09

17 Q. Okay. Have you ever given testimony in 09:09

18 court before? 09:09

19 A. When you say "testimony"? 09:09

20 Q. Gone into court, been sworn and 09:09

21 testified. 09:09

22 A. In court? 09:09

23 Q. In court. 09:09

24 A. No. 09:09

25 Q. How about in an arbitration 09:09

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1 proceeding?

09:09

2 A. Yes.

09:09

3 Q. What kind of arbitration proceeding  
4 was that?

09:10

09:10

5 A. It was an HR arbitration.

09:10

6 Q. Does that stand for human resources?

09:10

7 A. Yes.

09:10

8 Q. All right. So this was some sort of  
9 employment dispute at one of your jobs or your  
10 consulting arrangements?

09:10

09:10

09:10

11 A. It wasn't employment dispute, no.

09:10

12 Q. All right. Were you just a witness or  
13 had you been sued in the case or were you suing  
14 somebody else?

09:10

09:10

09:10

15 A. I was a witness.

09:10

16 Q. Have you only testified in one  
17 arbitration proceeding?

09:10

09:10

18 A. Just one arbitration, yes.

09:10

19 Q. Have you ever given a deposition such as  
20 we're about to do today?

09:10

09:10

21 A. Yes.

09:10

22 Q. How many times have you done that?

09:10

23 A. One time.

09:10

24 Q. What sort of case was it?

09:10

25 A. Probate.

09:10

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1 Q. All right. So you have never testified 09:11  
2 in a pharmaceutical products liability case in 09:11  
3 deposition? 09:11

4 A. No. 09:11

5 Q. How many times have you been retained as 09:11  
6 an expert witness in a pharmaceutical products 09:11  
7 liability case? 09:11

8 A. One time. 09:11

9 Q. Just this time? 09:11

10 A. Yes. 09:11

11 Q. All right. Now, do you know who Pete 09:11  
12 Miller is? 09:11

13 A. Yes. 09:11

14 Q. He's one of the Plaintiffs' lawyers in 09:11  
15 this Digitek litigation; correct? 09:11

16 A. Yes. 09:11

17 Q. When was the last time you met Pete 09:11  
18 Miller in person? 09:11

19 A. Yesterday. 09:11

20 Q. Where was that? 09:11

21 A. At the Sheraton. 09:11

22 Q. And how long did you spend with Pete 09:11  
23 Miller? 09:11

24 A. Several hours. 09:11

25 Q. Mr. Kerensky was just here a second 09:12



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1 ago. When did you first meet him in person? 09:12

2 A. Yesterday. 09:12

3 Q. How long did you spend with him? 09:12

4 A. A couple of hours. 09:12

5 Q. All right. When did you first meet 09:12

6 Mr. Fitzpatrick? 09:12

7 A. Yesterday. 09:12

8 Q. How long did you spend with him? 09:12

9 A. Several hours. 09:12

10 Q. And you've met Meghan before; correct? 09:12

11 A. Correct. 09:12

12 Q. Are there any other lawyers for the 09:12

13 Plaintiffs in the Digitek litigation with whom you 09:12

14 have met either in person or by telephone? 09:12

15 A. I'm not good with legal terms. So 09:12

16 Plaintiff, please? 09:12

17 Q. The people who are suing the 09:12

18 pharmaceutical companies. 09:12

19 A. Could you ask the question again, 09:12

20 please? 09:12

21 Q. Sure. Other than the people I've just 09:12

22 named, have you met with -- either in person or by 09:12

23 phone -- any other Plaintiffs' lawyers in the 09:12

24 Digitek litigation? 09:12

25 A. By phone, yes. 09:12

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1 Q. Who? 09:12

2 A. I don't recall who was on the 09:12

3 teleconference. 09:13

4 Q. How many people were on the 09:13

5 teleconference? 09:13

6 A. I don't know the exact number. 09:13

7 Q. And when was that telephone conference? 09:13

8 A. I believe it was in January of last 09:13

9 year. 09:13

10 Q. Now, I'll get in -- later into more 09:13

11 detail about what you did to prepare for today, 09:13

12 but do you know who Russ Soma is? 09:13

13 A. No. 09:13

14 Q. How about Mr. Kenny? 09:13

15 A. No. 09:13

16 Q. Jim Farley? 09:13

17 A. No. 09:13

18 Q. Karen Frank? 09:13

19 A. No. 09:13

20 Q. Each one of those people were hired by 09:13

21 the Plaintiffs' lawyers and wrote reports much 09:13

22 like you wrote here with your opinions about this 09:13

23 Digitek situation. 09:14

24 Have you ever read any of those reports? 09:14

25 A. Not to my knowledge, no. 09:14

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1 Q. Did any of the Plaintiffs' lawyers read 09:14  
2 to you from those reports? 09:14

3 A. No. 09:14

4 Q. Recently in December of 2010 we produced 09:14  
5 to the other side reports of our experts -- Lou 09:14  
6 Amsel, Martha Bennett, several other people. 09:14

7 Have you seen any of those reports? 09:14

8 A. Not that I recall. 09:14

9 Q. To the best of your knowledge, have any 09:14  
10 of the Plaintiffs' lawyers read to you from those 09:14  
11 reports? 09:14

12 A. Not that I recall. 09:14

13 Q. Have they told you in general what those 09:15  
14 reports contain and what their conclusions were? 09:15

15 A. No. 09:15

16 Q. Last June and then even last week I took 09:15  
17 and Mr. Anderton took and a Mr. Dean from my 09:15  
18 office took testimony from Russ Soma, Mr. Kenny, 09:15  
19 Karen Frank and Jim Farley; okay? 09:15

20 Have you seen any of those deposition 09:15  
21 transcripts? 09:15

22 A. Who are those individuals again? 09:15

23 Q. They are experts hired by the same 09:15  
24 people who hired you. 09:15

25 A. I don't recognize those names. 09:15

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1 Q. But have you read any of their 09:15  
2 deposition testimony? 09:16

3 A. Not that I recall. 09:16

4 Q. Did the Plaintiffs' lawyers read to you 09:16  
5 any excerpts from their transcripts? 09:16

6 A. No. 09:16

7 Q. When you met with these lawyers 09:16  
8 yesterday to get ready for today, did they tell 09:16  
9 you any of the kind of questions that you could 09:16  
10 expect from me? 09:16

11 A. Yes. 09:16

12 Q. All right. I assume that since you have 09:16  
13 both a college degree from a very reputable 09:16  
14 institution and a Ph.D., that you have had to 09:16  
15 study for and take examinations in your career; is 09:16  
16 that correct? 09:16

17 A. Yes. 09:16

18 Q. Did you ever have an occasion in your 09:16  
19 academic career when you studied real hard for a 09:16  
20 test but did poorly? 09:16

21 A. Specifically I don't recall. 09:17

22 Q. Did you ever have an occasion where you 09:17  
23 didn't study too hard at all but you did rather 09:17  
24 well? 09:17

25 A. Specifically I don't recall. 09:17

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1 Q. All right. Generally do you recall? 09:17

2 A. Vaguely. 09:17

3 Q. And is it your vague recollection that 09:17

4 those two things probably happened at some point 09:17

5 in your academic career? 09:17

6 A. Perhaps. 09:17

7 Q. All right. So if perhaps that happened, 09:17

8 you would agree with me logically that the amount 09:17

9 of work put in the process of studying did not 09:17

10 always necessarily correlate with the outcome; 09:18

11 right? 09:18

12 A. Could you say that again, please. 09:18

13 MR. MORIARTY: Can you read that back? 09:18

14 (Whereupon, the testimony was read 09:18

15 back by the court reporter, as recorded above) 09:18

16 THE WITNESS: I wouldn't agree with you 09:18

17 on that statement. 09:18

18 BY MR. MORIARTY: 09:18

19 Q. All right. Are you a golf fan? 09:18

20 A. No. 09:18

21 Q. Do you still shoot and skeet or trap 09:18

22 tournaments competitively? 09:18

23 A. No. 09:18

24 Q. Did you ever do that? 09:18

25 A. No. 09:18

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1 Q. Do you still coach? 09:18

2 A. I don't know if I understand what you 09:19

3 mean by "coach." 09:19

4 Q. Well, you have a website that talks 09:19

5 about your online shotgun classes. I think it 09:19

6 even says the word "coach." 09:19

7 Do you still do that? 09:19

8 A. I don't know if I understand what you 09:19

9 mean by "coach." 09:19

10 Q. Did you ever play any sports in high 09:19

11 school or -- 09:19

12 A. Yes. 09:19

13 Q. -- college? 09:19

14 A. Yes. 09:19

15 Q. Did you have coaches? 09:19

16 A. Yes. 09:19

17 Q. Elders, those with more experience who 09:19

18 taught you how to block or tackle or do freestyle 09:19

19 better? 09:19

20 A. Whatever sport. 09:19

21 Q. Okay. So you do have a website that 09:19

22 talks about you being the online coach? 09:19

23 A. No, it does not talk about me being the 09:19

24 online coach. 09:19

25 Q. Okay. I want to make sure I'm not 09:19

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1	misquoting anything. Is the name of the website	09:20
2	still claycoachonline.com?	09:20
3	A. It is.	09:20
4	Q. So the word "coach" is in the title of	09:20
5	the website; correct?	09:20
6	A. It is, correct.	09:20
7	Q. All right.	09:20
8	So what is it?	09:20
9	A. It's what it says on the web page there.	09:20
10	Q. Yeah, but what is it? Is it just a	09:20
11	video system that you sell?	09:21
12	A. It's more than a video system.	09:21
13	Q. But you don't do one-on-one coaching	09:21
14	with people; right?	09:21
15	A. Again, how do you define "coaching"?	09:21
16	Q. Teaching, encouraging, helping them	09:21
17	improve, trying to tell them about their	09:21
18	technique.	09:21
19	A. Professionally, for a fee?	09:21
20	Q. I didn't ask that. Do you do that at	09:21
21	all, whether for free or for a fee?	09:21
22	A. Coaching again, you know, I have	09:21
23	children. I coach all the time.	09:21
24	Q. Okay. Do you know the difference	09:21
25	between probability and possibility?	09:21

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1 A. From a legal term? 09:21

2 Q. Do you know the difference between 09:21

3 probability and possibility? 09:22

4 A. In what context? 09:22

5 Q. Any context. 09:22

6 A. No. 09:22

7 Q. So in your work as -- in the 09:22

8 pharmaceutical business and then as a 09:22

9 pharmaceutical consultant, you've never understood 09:22

10 the distinction between possibility and 09:22

11 probability? 09:22

12 A. I don't recall whether I've ever sat 09:23

13 down and thought about the difference between the 09:23

14 two. 09:23

15 Q. Okay. Do -- does adherence with GMPs 09:23

16 absolutely guarantee that a drug product will be 09:23

17 within its specifications all the time? 09:23

18 A. Could you say that again, please. 09:23

19 MR. MORIARTY: Would you read that back, 09:23

20 please? 09:23

21 (Whereupon, the testimony was read 09:23

22 back by the court reporter, as recorded above) 09:23

23 THE WITNESS: When you say GMPs, what 09:23

24 specifically are you talking about? 09:24

25 BY MR. MORIARTY: 09:24



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1 Q. Do you go by Dr. or Mr.? 09:24

2 A. Doctor. 09:24

3 Q. Okay. Dr. Bliesner, it has been 09:24

4 represented to me in your resume, in your website, 09:24

5 and in this lengthy report that you authored in 09:24

6 the Digitek case, that you are an expert in GMPs 09:24

7 for the pharmaceutical industry. 09:24

8 A. That is true. 09:24

9 Q. So why are you asking me what I mean by 09:24

10 GMPs? 09:24

11 A. I'm not sure if you understand the 09:24

12 definition of GMPs in some context. Some people 09:24

13 don't. 09:24

14 Q. Well, I do. 09:24

15 A. Okay. 09:24

16 Q. Okay. So can you answer my question? 09:24

17 A. Are we talking about 21 CFR 210 and 09:24

18 211? 09:24

19 Q. You got other GMPs for the 09:24

20 pharmaceutical industry? 09:24

21 A. There's currently industry practices 09:24

22 that sometimes people -- 09:24

23 Q. No, GMPs. 09:24

24 A. 21 CFR 210, 211? 09:24

25 Q. Yes, sir. 09:24

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1 A. Okay. And your question again, please. 09:24

2 Q. Does adherence with GMPs guarantee to 09:24

3 100 percent certainty that a drug product will 09:25

4 always meet its specifications as set forth in the 09:25

5 United States pharmacopeia? 09:25

6 A. Following the GMPs; right? I just want 09:25

7 to make sure I understand what your question is. 09:25

8 That you're saying if you follow the GMPs, then 09:25

9 there's a 100 percent guarantee that those 09:25

10 products will be -- what was the term? 09:25

11 Q. Within their specs. 09:25

12 A. Within their specs. There's no 09:25

13 guarantee, 100 percent guarantee. 09:25

14 Q. Okay. So you would agree with me that 09:25

15 adherence with GMPs increases the chances that 09:25

16 they will be within the specs; is that right? 09:25

17 A. Could you say that again, please? 09:26

18 MR. MORIARTY: Can you read it back, 09:26

19 please. 09:26

20 (Whereupon, the testimony was read 09:26

21 back by the court reporter, as recorded above) 09:26

22 THE WITNESS: The GMPs are a minimum 09:26

23 standard that's laid out by the federal 09:26

24 government. 09:26

25 BY MORIARTY: 09:26

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1 Q. That wasn't my question. My question is 09:26  
2 whether in your opinion adherence to the GMPs 09:26  
3 increases the chances that a drug product will 09:26  
4 meet its USP specs. 09:26

5 A. Possibly. 09:26

6 Q. Now you used the word "possibly." 09:26

7 A. Uh-huh. 09:26

8 Q. You told me earlier you don't know the 09:26  
9 difference between possibility and probability. 09:26  
10 So tell me what you mean by possibility or 09:26  
11 possibly in that answer. 09:26

12 A. Previously I actually said I've never 09:27  
13 sat down and thought about the difference between 09:27  
14 possibility and possibility. In this case you're 09:27  
15 asking me what I mean by possibly. 09:27

16 Q. Yeah, what do you mean by possibly in 09:27  
17 that answer? 09:27

18 A. Again, the GMPs are a minimum set of 09:27  
19 standards. They're designed to provide operating 09:27  
20 space if you will, to produce drugs that are safe 09:27  
21 and effective. And just because you follow them 09:27  
22 doesn't guarantee that everything you make falls 09:27  
23 into those categories. 09:27

24 Q. Okay. But if you adhere to them, does 09:27  
25 it increase the chances that you will meet the 09:27

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1 ANDA or NDA or USP specs for that drug? 09:27

2 A. I don't think that you can say just 09:28

3 because you follow the law it makes your product 09:28

4 going to be better. 09:28

5 Q. Okay. Have you ever heard of the 09:28

6 scientific method? 09:28

7 A. Yes. 09:28

8 Q. What is it? 09:28

9 A. Scientific method is a systematic means 09:28  
10 of developing a hypothesis, collecting data. 09:28

11 After doing experiments, analyzing the data, 09:28

12 drawing conclusions to try to support or detract 09:28

13 from your hypothesis. 09:28

14 Q. Is the scientific method best achieved 09:28

15 when you actually look at the underlying data as 09:28

16 opposed to somebody's interpretation of the data? 09:29

17 A. The scientific method is an approach to 09:29

18 collecting data. 09:29

19 Q. Okay. But in order to reach 09:29

20 scientifically valid conclusions, should you look 09:29

21 at the actual data as opposed to somebody's 09:29

22 interpretation of the data? 09:29

23 A. I don't know if I understand exactly 09:29

24 your question. 09:29

25 Q. Well, in your -- in your reading to 09:29

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1 prepare opinions in this case, you read this 09:29

2 article by Jerry Bauman and Robert Didomenico and 09:29

3 William Galanter about Digoxin; correct? 09:30

4 A. May I see it? 09:30

5 Q. Sure. That Post-It may even say what 09:30

6 the reference was in your report. 09:30

7 A. May I take a moment and confirm that 09:30

8 that is the article that I read? 09:30

9 Q. If you don't trust me, go ahead. 09:30

10 A. Okay. I need to step over here and grab 09:30

11 a -- 09:30

12 Q. Go ahead. Be careful with your 09:30

13 microphone cord. 09:30

14 MR. KERENSKY: Yeah, take it off. 09:30

15 THE WITNESS: I did review that 09:32

16 document. 09:32

17 BY MR. MORIARTY: 09:32

18 Q. The document is an article from the 09:32

19 medical literature, is it not? 09:32

20 A. Yes. 09:32

21 Q. Do you commonly read medical literature? 09:32

22 A. How do you define commonly? 09:32

23 Q. Well, how many articles have you read 09:32

24 about Digoxin in the past two years? 09:32

25 A. I don't recall. 09:32

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1 Q. Do you subscribe to any medical 09:32  
2 journals? 09:32

3 A. When you say subscribe, permanent 09:32  
4 subscription? 09:33

5 Q. Well, I don't expect that any 09:33  
6 subscription is permanent, but people subscribe to 09:33  
7 magazines for several years, maybe a year, maybe 09:33  
8 two, maybe for their entire career. 09:33

9 Do you subscribe to any medical journals? 09:33

10 A. I buy access to online medical journals, 09:33  
11 sites, and articles. 09:33

12 Q. And what sites are those? 09:33

13 A. I'd have to go back and look it up. 09:33

14 Q. But the bottom line is that this article 09:33  
15 doesn't just contain data. It contains analysis 09:33  
16 of data and editorial information about the data; 09:33  
17 correct? 09:33

18 A. What do you mean by editorial? 09:33

19 Q. Well, did you -- when did you last read 09:33  
20 that article? 09:34

21 A. Bless you. I don't recall. I guess 09:34  
22 probably early on when Miller firm contacted me 09:34  
23 somewhere in January. 09:34

24 Q. Do you read the newspaper? 09:34

25 A. Occasionally. 09:34

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1	Q.	Does it have an editorial section?	09:34
2	A.	Yes.	09:34
3	Q.	Do you know the editorial section from	09:34
4		the rest of the newspaper?	09:34
5	A.	Yes.	09:34
6	Q.	So you have some idea what editorial	09:34
7		means, don't you?	09:34
8	A.	Yes.	09:34
9	Q.	I'm handing you what has been marked as	09:34
10		Exhibit 78A.	09:35
11		Have you ever seen that before?	09:35
12	A.	Do you mind if I check my notes?	09:35
13	Q.	Oh, by all means. Let me ask you this	09:35
14		first: Do you have -- in this report that you	09:35
15		drafted, do you repeatedly refer to 21 United	09:35
16		States Code, Section 351, the section that defines	09:35
17		adulteration?	09:35
18	A.	Repeatedly.	09:36
19	Q.	Yeah.	09:36
20	A.	Can I see the report?	09:36
21	Q.	Do you ever refer to it? I'm not going	09:36
22		to quibble about the quantification. Do you ever	09:36
23		refer to this report?	09:36
24	A.	What's the number of that document?	09:36
25	Q.	21 United States Code, Section 351.	09:36

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1	A.	May I see the report, please?	09:36
2	Q.	You have your own copy?	09:36
3	A.	I do.	09:36
4	Q.	See if you ever refer to the section	09:36
5		that defines what adulterated drug product is --	09:36
6	A.	Say again the code that you are	09:36
7		specifically citing.	09:36
8	Q.	351 --	09:36
9	A.	21 CFR, 351?	09:36
10	Q.	Yeah. While you're looking, tell me how	09:36
11		long again you took to prepare for today's	09:36
12		deposition --	09:36
13	MR. KERENSKY:	Oh, my. Let's not get	09:36
14		testy. It's his first deposition. He's	09:36
15		taking his time. Let's not get testy.	09:36
16	MR. MORIARTY:	Okay. I'll withdraw that	09:36
17		question. See if you ever refer to this code	09:36
18		provision in your report.	09:36
19	THE WITNESS:	On page 9, difficulty in	09:37
20		manufacture of Digoxin tablets have been known	09:37
21		for some time and the concern to FDA --	09:37
22	THE COURT REPORTER:	Sir, slow down.	09:37
23	THE WITNESS:	Oh, I'm sorry.	09:37
24	BY MR. MORIARTY:		09:37
25	Q.	You don't have to read all that. Just	09:37



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1 tell me do you refer to it in the report, yes or 09:37

2 no? 09:37

3 A. 21 CFR, Part 310.500? 09:37

4 Q. 351 United States Code. Not the code of 09:37

5 Federal regulations, the United States code, 21 09:37

6 USC 351. It defines adulteration. Do you refer 09:37

7 to that in your report? What page are you on? 09:37

8 A. Fifteen. 09:39

9 Q. Let's -- let me withdraw the question 09:39  
10 and ask you another question. 09:39

11 A. Okay. 09:39

12 Q. Do you use the word "adulterated" in 09:39  
13 your report? Without looking, do you remember off 09:39  
14 the top of your head whether you used the word 09:39  
15 "adulterated" in your report? 09:39

16 A. Okay. 09:40

17 Q. Do you know what it means? 09:40

18 A. Yes. 09:40

19 Q. Okay. Let's look back at 78A, which is 09:40  
20 the statutory definition of adulteration; okay? 09:40  
21 Have you ever seen this before? 09:40

22 A. This document, 78A? 09:40

23 Q. Have you ever seen 21 USC Section 351, 09:40  
24 the definition of adulteration? 09:40

25 A. I have reviewed the Federal Food, Drug 09:41

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1 and Cosmetic Act.

09:41

2 Q. Okay.

09:41

3 A. Online.

09:41

4 Q. So --

09:41

5 A. But I do not commit the numbers to

09:41

6 memory.

09:41

7 Q. Okay. But you have seen this statute

09:41

8 before, whether you saw it on a piece of paper or

09:41

9 online; correct?

09:41

10 A. I'm not sure whether the document you

09:41

11 have in front of me is what I reviewed online.

09:41

12 Q. What does that mean? Do you think you

09:41

13 looked at a different version of the United States

09:41

14 code or a different provision of the code?

09:42

15 A. Possibly. Whatever version this was

09:42

16 that's on the website for the Government printing

09:42

17 office.

09:42

18 Q. Okay. Well, do you have a copy of this

09:42

19 in your own material that you printed and relied

09:42

20 on for purposes of your opinions in this case?

09:42

21 A. 78A?

09:42

22 Q. Mr. Bliesner, 21 United States Code,

09:42

23 section 351, whether it's marked as an exhibit or

09:42

24 not.

09:42

25 A. Let me check.

09:42

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1 MR. MORIARTY: Go off the record, 09:42

2 please. 09:42

3 THE VIDEOGRAPHER: The time is now 09:42

4 9:43 a.m. and we're going off the record 09:42

5 briefly. 09:42

6 (Short break) 09:57

7 THE VIDEOGRAPHER: The time is 9:58 a.m. 09:57

8 We're back on the record. 09:57

9 BY MR. MORIARTY: 09:57

10 Q. In the time that you did spend looking 09:57

11 in materials, you didn't find either 21 USC 09:58

12 section 351 or 21, Code of Federal Regulations, 09:58

13 Section 351, did you? 09:58

14 A. In my stuff? 09:58

15 Q. Correct. 09:58

16 A. No, I did not. 09:58

17 Q. But because the word adulteration is in 09:58

18 your written report, presumably you know what that 09:58

19 means; correct? 09:58

20 A. Yes. 09:58

21 Q. So what I've placed before you is 09:58

22 Exhibit 78A. It is the United States Code 09:58

23 definition of adulteration. 09:58

24 A. Okay. 09:58

25 Q. And I'm going to refer to Section A2(b) 09:58



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1	when GMPs are not complied with?	10:00
2	A. Yes.	10:00
3	Q. All right. Now, does that section A2(b)	10:00
4	say anything about drugs actually being outside	10:00
5	their specifications?	10:00
6	A. The word specification is not here.	10:00
7	Q. Does it say anything about drugs being	10:00
8	dangerous to consumers?	10:00
9	A. It applies safety.	10:00
10	Q. Where does the word --	10:01
11	A. "As to safety and has the identity and	10:01
12	strength."	10:01
13	Q. I'm asking whether it says anything	10:01
14	about danger to consumers.	10:01
15	A. It does not say anything in that	10:01
16	sentence.	10:01
17	Q. Does it use the word -- does A2(b) use	10:01
18	the word defective?	10:01
19	A. The word defective is not here.	10:01
20	Q. Does A2(b) say anything about whether	10:01
21	these adulterated products are possibly or likely	10:01
22	defective or out of specification? Does that	10:01
23	phrase or wording appear anywhere in the statute?	10:02
24	A. Could you say that again, please.	10:02
25	MR. MORIARTY: Can you read that back?	10:02

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1 (Whereupon, the testimony was read 10:02

2 back by the court reporter, as recorded above) 10:02

3 THE WITNESS: Not right here in this 10:02

4 sentence, no. 10:02

5 BY MR. MORIARTY: 10:02

6 Q. To the best of your knowledge, does that 10:02

7 phrase or wording appear in the Code of Federal 10:02

8 Regulations that mirrors this statutory 10:02

9 definition? 10:02

10 A. I couldn't say because this regulation 10:02

11 is not one that we refer to in the industry. We 10:02

12 stay with the GMPs. This is the higher-level 10:02

13 document and the lawyers are concerned with this. 10:02

14 We are not, at the operational level. 10:03

15 Q. And when you say the GMPs, are you 10:03

16 talking about Code of Federal Regulations, Title 10:03

17 21, Section 210? 10:03

18 A. 210 and 211. 10:03

19 Q. Okay. So I'm handing you what's Exhibit 10:03

20 75. 10:03

21 A. Yes. 10:04

22 Q. You've seen that before; correct? 10:04

23 A. I have. 10:04

24 Q. All right. So -- 10:04

25 A. Not this particular exhibit, but I have 10:04

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1 seen 21 CFR 210 and 211. 10:04

2 Q. So when we look at 210.1(b), it says, 10:04

3 "The failure to comply with any regulations 10:04

4 set forth in this part and in parts 211 through 10:04

5 226 of this chapter, in the manufacture, 10:04

6 processing, packing and folding of a drug, shall 10:04

7 render such drug to be adulterated under section 10:04

8 501 A(2)(b) of the Act, and such drug as well as 10:04

9 the person who is responsible for the failure to 10:05

10 comply shall be subject to regulatory action." 10:05

11 Did I read that correctly? 10:05

12 A. Yes, sir. 10:05

13 Q. Now, is it -- is it your understanding 10:05

14 that this lawsuit is not a regulatory action? 10:05

15 A. Regulatory action on the part of the 10:05

16 Government, is that -- is that what you're talking 10:05

17 about? 10:05

18 Q. No, I'm asking is this lawsuit -- is it 10:05

19 your understanding that this lawsuit is or is not 10:05

20 a regulatory action? 10:05

21 A. It is not a regulatory action by the 10:05

22 Federal Government as I understand it. 10:05

23 Q. Okay. And that's what you understand 10:05

24 Exhibit 75, section 210.1(b) to mean, is a 10:05

25 regulatory action by the Federal Government; 10:06

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1 correct? 10:06

2 A. That's how I interpret it, yes. 10:06

3 Q. Now, does anything in 210.1(b) refer to 10:06

4 out of specification, dangerous, or defective -- 10:06

5 by the way, please don't write on the exhibits. 10:06

6 A. Sorry. 10:06

7 Q. You really don't need your pen. 10:06

8 MR. KERENSKY: No, he can use his pen to 10:06

9 help him find it, but he will not write on it. 10:06

10 MR. MORIARTY: Put the cap on. 10:06

11 THE WITNESS: I won't write on your 10:06

12 documents. Sorry. 10:06

13 MR. MORIARTY: They're not mine anymore. 10:06

14 Once I give them to you, they're not mine. 10:06

15 THE WITNESS: I'm sorry. 10:06

16 BY MR. MORIARTY: 10:06

17 Q. The question is does 210.1(b) say 10:06

18 anything about out of specification, dangerous, or 10:06

19 defective? 10:06

20 A. It does not say out of specification, 10:07

21 dangerous, or defective in here. 10:07

22 Q. Does Section A say those words? 10:07

23 A. It's dangerous specifications and -- 10:07

24 Q. Dangerous, out of specification, or 10:07

25 defective. 10:07



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1	A.	No.	10:07
2	Q.	All right. May have that Exhibit 75?	10:07
3	A.	Sure. Can I have yours?	10:07
4		MR. KERENSKY: Sure.	10:07
5		BY MR. MORIARTY:	10:07
6	Q.	Did you -- you wrote on that one, too.	10:07
7		Terry, can I have your 78(a)?	10:07
8	A.	Sorry.	10:07
9	Q.	All right. So at some point last	10:07
10		winter, last spring, the Plaintiffs' lawyers sent	10:08
11		you material to review; correct?	10:08
12	A.	Yes.	10:08
13	Q.	Did you review it carefully?	10:08
14	A.	Yes.	10:08
15	Q.	Did you talk to them before you wrote	10:08
16		this report?	10:08
17	A.	In relation to the documents I was	10:08
18		getting, those types of things, yes.	10:08
19	Q.	Yeah. And by the way, when we talk	10:08
20		about your report, we're talking about Exhibit 92,	10:08
21		are we not?	10:08
22	A.	I'm not sure because the page numbers	10:09
23		don't match up in content.	10:09
24	Q.	Did you write two versions of the	10:09
25		report?	10:09

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1	A.	No.	10:09
2	Q.	Are you sure?	10:09
3	A.	Yeah.	10:09
4	Q.	Well, does Exhibit 94 match the one you	10:09
5		have with you?	10:09
6	A.	No, the page numbers are off, which may	10:09
7		be a matter of printing possibly.	10:09
8	Q.	Okay. Do 92 and 94 appear to be your	10:09
9		report, even though the page numbers may be off in	10:09
10		some way?	10:10
11	A.	They appear to be my report.	10:10
12	Q.	Okay. So in the process, you reviewed	10:10
13		material, you spoke with the lawyers who retained	10:10
14		you and then ultimately you drafted a report;	10:10
15		correct?	10:10
16	A.	Yes.	10:10
17	Q.	And were you aware that in this process	10:10
18		of drafting the report, what you were doing was	10:10
19		putting lawyers like me who represent the	10:10
20		pharmaceutical manufacturer on notice of what your	10:10
21		opinions were in this case?	10:10
22	A.	Can you say that again, please?	10:10
23	Q.	As you went through this process, did	10:10
24		you realize that the purpose of the report was not	10:10
25		only to organize your thoughts but it was to put	10:10

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1 people like me on notice of what your opinions 10:10

2 were? 10:10

3 A. On notice I'm assuming is reporting the 10:10

4 information that I saw and the conclusions I came 10:10

5 to, yes. 10:10

6 Q. Yeah, put me on notice so that when I 10:11

7 came to question you, I would have some idea as a 10:11

8 starting point what your thoughts were; right? 10:11

9 A. I'm actually having difficulty here. On 10:11

10 notice means different things to me than it may 10:11

11 mean to you. 10:11

12 Q. Well, in some way you were communicating 10:11

13 to readers -- including people like me -- what 10:11

14 your opinions were; right? 10:11

15 A. Yes. 10:11

16 Q. And you tried to do the best you could 10:11

17 to make your report thorough so that you would 10:11

18 remember in an organized fashion what your 10:11

19 opinions were; correct? 10:11

20 A. Correct. 10:11

21 Q. And these lawyers like Fred Thompson, 10:11

22 and Meghan and Mike would know what your opinions 10:11

23 were; right? 10:11

24 A. Correct. 10:11

25 Q. And the court presumably, if it read 10:11

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1 your report, would know what your opinions are; is 10:11

2 that right? 10:11

3 A. Correct, yes. 10:11

4 Q. Now, let's go to page 6. And what are 10:11

5 you -- 10:11

6 A. Which version would you like me to use? 10:11

7 Q. Well, pick 92 or 94. Let's see if 10:12

8 they're the same. 10:12

9 A. Okay. I'll look at 92. 10:12

10 Q. Sure. Page 6. 10:12

11 A. Page 6? 10:12

12 Q. Lower right hand corner. Look at the 10:12

13 top. Is paragraph four the first thing on the 10:12

14 page? 10:12

15 A. Review of Amide/Actavis Status of 10:12

16 Compliance with cGMPs: My approach? 10:12

17 Q. Yes. 10:12

18 A. Yes. 10:12

19 Q. All right. By the way, is that the same 10:12

20 in 94? 10:12

21 A. Let's take a look. It is. 10:12

22 Q. And the same as the version you brought 10:12

23 with you? 10:12

24 A. No. 10:12

25 Q. Can I see the one you brought with you? 10:12

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1 A. Yeah. It appears to be a formatting 10:12

2 page thing. 10:13

3 Q. Okay. So it says here: "In order to 10:13

4 accurately evaluate the status of Amide/Actavis's 10:13

5 status of compliance with the CGMPs, I took the 10:13

6 following approach." 10:13

7 Did I read that correctly? 10:13

8 A. You did. 10:13

9 Q. Now did the lawyers who retained you in 10:13

10 this litigation tell you that your charge or your 10:13

11 job in this case was to evaluate the status of my 10:13

12 client's compliance with the GMPs? 10:13

13 A. Yes. 10:14

14 Q. And they did not tell you that your 10:14

15 charge or your task in this case was to help them 10:14

16 determine if out of specification Digitek actually 10:14

17 reached the hands of consumers; correct? 10:14

18 A. My guidance from them was fairly 10:14

19 general, included evaluate, in your opinion, the 10:14

20 status of compliance with GMPs and how that may 10:14

21 have affected a product that was potentially 10:14

22 dangerous getting to market, Digitek being the 10:14

23 one. 10:14

24 Q. Potentially dangerous? 10:14

25 A. Uh-huh. 10:14

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1 Q. Right? 10:15

2 A. Uh-huh. 10:15

3 Q. You have to answer out loud. 10:15

4 A. Yes, I'm sorry, yes. 10:15

5 Q. Phil doesn't understand uh-huh, huh-uh, 10:15

6 and shakes and nods; okay? 10:15

7 A. Yes, sir. 10:15

8 Q. So in bullet point number one, you 10:15

9 assumed that Amide and Actavis was a new 10:15

10 consulting client needing assistance with 10:15

11 determining their level of compliance with the 10:15

12 GMPs. Is that what it says there? 10:15

13 A. It does. 10:15

14 Q. And you performed a paper audit of the 10:15

15 facility to determine past and current status of 10:15

16 compliance; right? 10:15

17 A. That is correct. 10:15

18 Q. And then you list what your audit 10:15

19 included; is that right? 10:15

20 A. That's correct. 10:15

21 Q. Now, how long have you been in the 10:15

22 consulting business in the pharmaceutical 10:15

23 industry? 10:15

24 A. About 12, almost 13 years. 10:15

25 Q. In those 12 to 13 years, how many times 10:15

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1 have you actually been engaged by a pharmaceutical 10:15

2 company to do a project? 10:16

3 A. A project? Any type of project? 10:16

4 Q. Any type of project. 10:16

5 A. How many times? 10:16

6 Q. Yeah. 10:16

7 A. It's numerous. I'd have to really sit 10:16

8 down and think about it. 10:16

9 Q. How many times have you been asked by a 10:16

10 consulting client in those 12 to 13 years to 10:16

11 assess their status of compliance with GMPs? 10:16

12 A. At least five. 10:16

13 Q. In general, in the five times that you 10:16

14 were retained by a pharmaceutical client to assess 10:16

15 their GMP status, how many times in those five did 10:16

16 you look at batch records? 10:17

17 A. It's tough to say. Numerous. 10:17

18 Q. Okay. And when you did, did you look at 10:17

19 a lot of batch records? 10:17

20 A. Depends on how you're going to define "a 10:17

21 lot." 10:17

22 Q. Did you look at more than one batch 10:17

23 record? 10:17

24 A. Yes. 10:17

25 Q. Did you look at more than two? 10:17

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1 A. Yes. 10:17

2 Q. Did you look at annual reports or annual 10:17

3 data reviews in these five times when you were 10:17

4 asked by pharmaceutical companies to assess their 10:17

5 compliance? 10:17

6 A. Yes. 10:17

7 Q. Did you look at FDA 484 testing if it 10:17

8 was available? 10:18

9 A. No. 10:18

10 THE VIDEOGRAPHER: We have five minutes 10:18

11 left on the tape. 10:18

12 BY MR. MORIARTY: 10:18

13 Q. Do you know what US or FDA 484 testing 10:18

14 is? 10:18

15 A. Generally. 10:18

16 Q. Okay. If the pharmaceutical clients 10:18

17 that you hired had hired other companies to help 10:18

18 them remediate 483s and warning letters, did you 10:18

19 look at those remediation documents? 10:18

20 A. Yes. 10:18

21 Q. Did you look at any sort of independent 10:18

22 testing of the product if it was available to you? 10:18

23 A. Yes. 10:18

24 Q. And just to wrap up this segment before 10:18

25 the tape expires, I assume that you, when you 10:18



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1 looked at things like batch records and annual 10:18  
2 reports and annual data reviews, you would have 10:18  
3 been looking at finished product test results for 10:18  
4 various products; is that true? 10:19

5 A. Yes, and active pharmaceutical 10:19  
6 ingredients as well. 10:19

7 MR. MORIARTY: Let's take our tape 10:19  
8 break. 10:19

9 THE VIDEOGRAPHER: The time is 10:19  
10 a.m. We're going off the record 10:19  
11 briefly. 10:19

12 (Short break) 10:22

13 THE VIDEOGRAPHER: The time is now 10:22  
14 10:23 a.m. We are back on record. This is 10:22  
15 the beginning of tape two. 10:22

16 BY MR. MORIARTY: 10:22

17 Q. So getting back to how you did this 10:22  
18 paper audit, another thing that I forgot to ask 10:22  
19 you about is when you have checked GMP compliance 10:22  
20 for some of your pharmaceutical clients, do you 10:23  
21 look at process validation studies? 10:23

22 A. I have, yes. 10:23

23 Q. All right. So in this litigation, how 10:23  
24 many process validation studies for Digitek did 10:23  
25 you look at? 10:23

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1 A. None were made available to me that I 10:23

2 recall. 10:23

3 Q. Did the Plaintiffs' lawyers make 10:23

4 available to you an online repository of 10:23

5 documents? 10:23

6 A. Yes. 10:23

7 Q. Did you look through there to see what 10:23

8 was in there? 10:23

9 A. Yes. 10:23

10 Q. And -- 10:23

11 A. In detail. 10:23

12 Q. And process validation studies were not 10:23

13 there? 10:23

14 A. At the time I reviewed it, not to my 10:23

15 knowledge. 10:23

16 Q. All right. Now this is Exhibit 1. It's 10:23

17 the Amide process validation report for Digitek, 10:23

18 .125, at the batch size of 1,600,000 tablets. 10:24

19 Have you ever seen that before? 10:24

20 A. May I check my documents? It may have 10:24

21 been associated with an investigation. 10:24

22 Q. Do you have a list so that we don't have 10:24

23 to watch you thumb through the boxes? I mean you 10:24

24 told me a minute ago you don't recall seeing 10:24

25 them. I'm just trying to verify whether you've 10:24

25 THE VIDEOGRAPHER: On. Would you like me 10:26

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1	to go off?	10:26
2	MR. MORIARTY: Sure.	10:27
3	THE VIDEOGRAPHER: The time is	10:27
4	a.m. We're going off the record	10:27
5	briefly.	10:27
6	(Short break)	10:30
7	THE VIDEOGRAPHER: The time is	10:30
8	a.m. We are back on the record.	10:30
9	BY MR. MORIARTY:	10:30
10	Q. So, so far, we've talked about 1, 1(a)	10:30
11	and 1(b). The question is are those in your	10:30
12	documents that you reviewed to formulate opinions	10:30
13	in this case?	10:30
14	A. Just so you know, this is a list of	10:30
15	every document I reviewed online. I just want to	10:32
16	make sure that I'm not misspeaking, so...	10:32
17	Q. Did you print everything you reviewed	10:32
18	online?	10:32
19	A. No, there's just too much. It does not	10:32
20	appear that I had access nor reviewed process	10:33
21	validation.	10:33
22	Q. Okay. So Exhibit 2, just for	10:33
23	completeness, this is the process validation for	10:33
24	the 4.2 million tablet batch sizes for .25	10:33
25	Digoxin. You haven't seen this document?	10:34

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1 A. No. 10:34

2 Q. And Exhibit 3, did you know that 10:34

3 Digitek, like other Digoxin products, used to be 10:34

4 made in .5 milligrams? 10:34

5 A. I don't recall that fact. 10:34

6 Q. No? This is Exhibit 3. 10:34

7 A. Uh-huh. 10:34

8 Q. This is the process validation for the 10:34

9 .5 milligram Digitek. Have you ever seen that 10:34

10 document? 10:34

11 A. No. 10:34

12 Q. May I see that compendium of documents 10:34

13 you reviewed online but you did not print or put 10:34

14 in your boxes? 10:34

15 A. Sure. 10:34

16 Q. I'm going to put an exhibit sticker on 10:34

17 this. 10:34

18 A. Sure. 10:34

19 Q. These go together, these two? 10:34

20 A. Yes. 10:34

21 Q. Okay. 10:34

22 A. One's for Mylan documents and others 10:34

23 were a Plaintiffs' exhibit, if I'm not mistaken. 10:34

24 Q. Okay. So. I am going -- 10:35

25 A. They were organized differently on the 10:35

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1 website. 10:35

2 Q. I'm going to put Exhibit 107 on the list 10:35

3 you made of the Mylan documents and 108 on the 10:35

4 Plaintiffs' exhibits; okay? 10:35

5 (Whereupon, Exhibits 107 and 108 were marked 10:35

6 for identification) 10:35

7 A. Okay. 10:35

8 Q. I partially obscured your e-mail address 10:35

9 for this one; okay. 10:35

10 Tell us all in general what process validation 10:35

11 is briefly. 10:35

12 A. Briefly, process validation is just the 10:35

13 process of following a protocol, delineating those 10:35

14 critical components in the manufacturing process 10:35

15 that need to be varied and see the observing 10:35

16 effect on the product you have. 10:36

17 Q. Once a pharmaceutical company has 10:36

18 validated a process in manufacturing a 10:36

19 pharmaceutical -- 10:36

20 A. Uh-huh. 10:36

21 Q. -- does that in essence mean that they 10:36

22 have shown that they can make the drug within its 10:36

23 specifications consistently? 10:36

24 A. That is the purpose of process 10:36

25 validation in general. However, I will tell you 10:36

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1 this: I am not a process validation expert. I 10:36  
2 support process validation from a laboratory, 10:36  
3 cross-functional standpoint, including reviewing 10:36  
4 the protocols and looking at the samples that are 10:36  
5 to be tested and how they are to be tested. 10:36

6 Q. Okay. So you have been involved in 10:36  
7 process validation from the what I would call QC 10:36  
8 or lab perspective; right? 10:36

9 A. No, analytical R&D. 10:36

10 Q. Okay. 10:36

11 A. Which is different than a QC. 10:36

12 Q. Not even finished product testing? 10:36

13 A. No, that's not true. I've done both. 10:36

14 Q. Okay. But the fact is that when you 10:37  
15 have a process validation for the manufacturer of 10:37  
16 a pharmaceutical, it includes the equipment you're 10:37  
17 going to use to blend it, press it, package it, 10:37  
18 and all the steps you're going to take to test it 10:37  
19 to assure as best you can that you consistently 10:37  
20 produce the product within its ANDA or NDA or USP 10:37  
21 specs; correct? 10:37

22 A. In general I'd say that's a fair 10:37  
23 assessment. 10:37

24 Q. And when the FDA approved the ANDA for 10:37  
25 Digitek, at least at some point the FDA was 10:37

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1 satisfied that the processes to make that drug had 10:37

2 been validated; correct? 10:37

3 A. By review of the application, what was 10:38

4 in the application and what was associated with 10:38

5 the process validation, yes, at that time. 10:38

6 Q. Okay. Now have you been in the 10:38

7 pharmaceutical business long enough to know what 10:38

8 the batch certification program was? 10:38

9 A. After reviewing the documents related to 10:38

10 this case, yes. 10:38

11 Q. All right. And batch certification was 10:38

12 when you actually had to submit samples of product 10:38

13 to the FDA from a batch before you could ship it 10:38

14 to market; correct? 10:38

15 A. All I know is what I'm familiar with, 10:38

16 with this case, that Digitek was part of that. As 10:38

17 far as other drugs, I couldn't say. 10:38

18 Q. All right. So, for example, have you 10:38

19 ever seen Exhibit 4, which was a letter from FDA 10:38

20 to what later became my client verified or 10:38

21 certifying that these batches could be 10:39

22 distributed? 10:39

23 Have you ever seen that letter? 10:39

24 A. Possibly. 10:39

25 Q. Have you ever seen Exhibit 5? Please 10:39



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1 take a look at Exhibit 5. 10:39

2 A. Uh-huh. 10:39

3 Q. I will tell you that it's a letter from 10:39

4 July 1995 from the FDA to Amide exempting it from 10:39

5 the batch certification process. 10:39

6 Have you ever seen that? 10:39

7 A. I don't recall. 10:39

8 Q. At least -- 10:40

9 A. It's possible it could be part of the 10:40

10 ANDA package and I may have seen it, but I'm not 10:40

11 sure. 10:40

12 Q. At least as of that time -- 10:40

13 A. Uh-huh. 10:40

14 Q. -- FDA was satisfied that Actavis was 10:40

15 making this product within its specifications 10:40

16 consistently so that it didn't need the advance 10:40

17 approval to ship product to market. Is that 10:40

18 essentially what that says? 10:40

19 A. Let me take a look at this. As I 10:40

20 understand the batch certification process back in 10:40

21 1995, from what I have reviewed from these case 10:40

22 documents, I'd say that statement is accurate. 10:40

23 Q. All right. Now have you heard the 10:40

24 phrase in the pharmaceutical business a process 10:40

25 that is in control? 10:40

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1	A.	Yes.	10:40
2	Q.	So part of process validation is to	10:40
3		assure that your process is in control; correct?	10:41
4	A.	Correct.	10:41
5	Q.	Now, let's get back to your report and	10:41
6		whether you look at --	10:41
7	A.	Whatever copy, yeah.	10:41
8	Q.	And just so you know, I think one	10:41
9		version was produced in the Philadelphia	10:41
10		litigation and the other was produced in the MDL.	10:41
11		I think that's what the difference is.	10:41
12	A.	Okay.	10:41
13	Q.	So you'll notice that the one on your	10:41
14		right, 94 --	10:41
15	A.	Yes.	10:41
16	Q.	-- has a Philadelphia caption on it;	10:41
17		okay? See that up top?	10:41
18	A.	Yes.	10:41
19	Q.	So look at 92, which was your MDL	10:41
20		report. Now in the first paragraph, where you say	10:41
21		purpose.	10:41
22	A.	Uh-huh.	10:41
23	Q.	In the last sentence you talk about a	10:41
24		high likelihood that adulterated drug product made	10:41
25		it to the marketplace.	10:42

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1 Do you see that? 10:42

2 A. Yes. 10:42

3 Q. And then if you go all the way back to 10:42

4 your conclusion at page 21, you talk about 10:42

5 adulterated product making it to the marketplace. 10:42

6 Do you see that? 10:42

7 A. Yes, I do. 10:42

8 Q. Now, I reviewed your report pretty 10:42

9 carefully. 10:42

10 A. Uh-huh. 10:42

11 Q. Nowhere do I see you make any statement 10:42

12 in this 21 page report that Digitek which was 10:42

13 actually out of its specifications made it to the 10:42

14 hands of consumers. 10:42

15 Am I correct about that? 10:42

16 A. In this report? 10:42

17 Q. Yes, sir. 10:42

18 A. I don't know if I agree with that. 10:42

19 Q. Let me ask that a different way. 10:43

20 A. Uh-huh. 10:43

21 Q. In the opinions section of your report 10:43

22 -- 10:43

23 A. Uh-huh. 10:43

24 Q. -- anywhere do you say that out of 10:43

25 specification Digitek made it to the hands of 10:43

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1 consumers or to the marketplace? 10:43

2 A. Those specific words, out of 10:43

3 specification? 10:43

4 Q. Yes, sir. 10:43

5 A. I don't believe I used the term "out of 10:44

6 specification." However, if you look at 22, we 10:45

7 have an instance it goes back to my references 10:45

8 that there was a pharmacist in Bellingham, 10:45

9 Washington, who found double-thick tablets which 10:45

10 would be out of specification. 10:45

11 Q. Okay. I'm asking in your opinions 10:45

12 section in your report, that would be a fact upon 10:45

13 which you would rely. I'm asking if in any 10:45

14 opinion section? 10:45

15 A. Used the word specification? 10:45

16 Q. Yeah. No, out of specification. 10:45

17 A. Not that I recall. 10:45

18 Q. Is there anywhere in the opinions 10:45

19 section in your report where you render an opinion 10:45

20 that dangerous Digitek made it to the marketplace 10:45

21 or into the hands of consumers? 10:45

22 A. I did not use the word dangerous; 10:45

23 however, you know it's -- 10:45

24 Q. Is there any place? 10:45

25 MR. KERENSKY: Wait. He just said 10:45

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1	"however."	10:45
2	MR. MORIARTY: I don't. I want answers	10:45
3	to my questions.	10:45
4	MR. KERENSKY: No, he gets to say	10:45
5	"however", if he wants to say "however."	10:46
6	MR. MORIARTY: Go ahead with your	10:46
7	however.	10:46
8	THE WITNESS: However, you look through	10:46
9	the literature that was available to me, it's	10:46
10	obvious that Digitek which was out of	10:46
11	specification -- thick, thin, whatever -- has	10:46
12	showed up several times in the marketplace.	10:46
13	BY MR. MORIARTY:	10:46
14	Q. We'll get to that.	10:46
15	A. Okay.	10:46
16	Q. Is there anywhere in your report where	10:46
17	you render an opinion that defective Digitek made	10:46
18	it to the marketplace?	10:46
19	A. I don't believe I used the word	10:46
20	"defective."	10:46
21	Q. Your conclusion in the both the	10:46
22	beginning and end is that it was adulterated;	10:46
23	correct?	10:46
24	A. Digitek that was not manufactured to its	10:46
25	specifications made it to the market; therefore,	10:46

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1 by definition, it would be adulterated. 10:46

2 Q. Can you identify a single Plaintiff in 10:46

3 this litigation who received out-of-specification 10:46

4 Digitek? 10:47

5 A. An individual per se? 10:47

6 Q. Yeah. 10:47

7 A. I'm not familiar with the individuals 10:47

8 who found the cases. 10:47

9 Q. Now, you know what a -- in general what 10:47

10 a double-thick tablet is, do you not? 10:47

11 A. As described in the documents that I 10:47

12 reviewed, I'd say yes. I've personally never seen 10:47

13 any double-thick tablet. 10:47

14 Q. Not even in this litigation, nobody has 10:47

15 ever shown you one; right? 10:47

16 A. From what I understand, nobody retained 10:47

17 any of the double-thick tablets. 10:47

18 Q. Do you have some understanding that 10:47

19 somebody actually had one and threw it away? 10:47

20 A. I wouldn't say that I know they threw it 10:47

21 away. I know they had them. 10:47

22 Q. Oh, tell me who had one. 10:47

23 A. Well, first the pharmacist had one. 10:47

24 Q. In 2003 or 4? 10:48

25 A. I will take a look and see what date 10:48

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1	that was.	10:48
2	Q. Trust me. It was 2003 or 2004 if you're	10:48
3	talking about the Bellingham, Washington	10:48
4	incident.	10:48
5	A. All right.	10:48
6	Q. Okay. So was 2003 Digitek recalled?	10:48
7	A. I don't recall.	10:48
8	Q. When was the first batch of recalled	10:48
9	Digitek manufactured?	10:48
10	A. I have to look.	10:48
11	Q. Do you remember what the FDA said about	10:48
12	the 2004 incident?	10:48
13	A. No.	10:48
14	Q. Do you know what an establishment	10:48
15	inspection report is?	10:48
16	A. I do.	10:48
17	Q. Let me make sure I didn't write on	10:48
18	this. This is the EIR from the fall of 2004.	10:48
19	A. Uh-huh.	10:49
20	Q. First of all, you know that that	10:49
21	double-thick tablet incident was investigated by	10:49
22	Amide; correct?	10:49
23	A. Investigated as part of a manufacturing	10:49
24	investigation?	10:49
25	Q. Yes.	10:49

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1	A.	Yes.	10:49
2	Q.	And you know that it was reported to the	10:49
3	FDA	in a field alert; correct?	10:49
4	A.	I've never seen a field alert.	10:49
5	Q.	They didn't make that available to you?	10:49
6	A.	Not that I recall. It may have been on	10:49
7	the list,	but I do not specifically require seeing	10:49
8	a field alert.		10:50
9	MR. FITZPATRICK:	And could you pass	10:50
10	Exhibit 5?		10:50
11	MR. MORIARTY:	Yeah, but I need my copy	10:50
12	for a second,	if you don't mind.	10:50
13	BY MR. MORIARTY:		10:50
14	Q.	Turn to page 6 of the 2004 EIR.	10:50
15	A.	Exhibit 20?	10:50
16	Q.	Yes, sir. And first of all, I don't	10:50
17	remember.	Have you seen this EIR as part of your	10:50
18	review?		10:50
19	A.	No, this is for a preapproval inspection	10:50
20	for another product.		10:50
21	Q.	Well, look at page 6. You see the bold,	10:50
22	centered,	in all cap, field alert reporting?	10:50
23	A.	I do.	10:51
24	Q.	All right. It describes this report	10:51
25	from a pharmacist	of a quote "thick tablet."	10:51



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1 Do you see that? 10:51

2 A. I do. 10:51

3 Q. From lot 3611(a), with an expiration in 10:51

4 December of '04. 10:51

5 Do you see that? 10:51

6 A. I do. 10:51

7 Q. Now, certainly -- withdraw that. 10:51

8 New Jersey District Compliance Branch was 10:51

9 notified by the site and the investigation was 10:51

10 completed at the time of inspection; correct? 10:51

11 A. That's what it says. 10:51

12 Q. In other words, the company told FDA 10:51

13 about this incident; right? 10:51

14 A. Uh-huh. 10:51

15 Q. That's a yes? 10:51

16 A. At the time of the inspection, yes. 10:51

17 Q. All right. And the field alert report 10:51

18 noted quote, "The most probable cause of the thick 10:51

19 tablet was a set up problem"; correct? Is that 10:51

20 what it says? 10:52

21 A. It says manufacturing set up problem. 10:52

22 Set up, yes. 10:52

23 Q. And then it talks about procedural 10:52

24 enhancements and training, does it not? 10:52

25 A. Yes. 10:52

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1 Q. And then it says, "No additional 10:52  
2 complaints or reports of thick tablets have been 10:52  
3 received for this high volume product. The event 10:52  
4 was considered an isolated incident and corrective 10:52  
5 actions were put in place to prevent its 10:52  
6 reoccurrence. Corrective actions were verified 10:52  
7 during the inspection." 10:52

8 Did I read that correctly? 10:52

9 A. Corrective actions, procedural 10:52  
10 enhancements, review of complaint files were 10:52  
11 verified during inspection. 10:52

12 Q. Correct? 10:52

13 A. Yes, that's what it says. 10:52

14 Q. Do you have some reason to disagree with 10:52  
15 the FDA that this event was an isolated incident? 10:52

16 A. Yes, I do. 10:52

17 Q. Okay. Show me any evidence that you 10:52  
18 have that any extra thick tablet made it into the 10:52  
19 hands of a pharmacist or consumer after 2004. 10:52

20 MR. FITZPATRICK: Let me interpose an 10:53  
21 objection as to form. 10:53

22 BY MR. MORIARTY: 10:53

23 Q. What are you looking for? 10:53

24 A. I'm looking for an e-mail chain that 10:53  
25 shows a pharmacist somewhere in Massachusetts 10:53

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1 found double-thick tablets in a card. 10:53

2 Q. Excellent. Here it is. Okay. I'm 10:53

3 showing you Exhibit 59. Is that the document that 10:54

4 you are looking at from your own file? 10:54

5 A. No, it's not. 10:55

6 Q. Yeah, it's not because my staff didn't 10:55

7 copy the second page. Let me see that, please. 10:55

8 A. Sure. The yellow tab is the specific 10:55

9 reference to it. 10:55

10 Q. Okay. That is supposed to be Exhibit 10:55

11 59. 10:55

12 A. Okay. 10:55

13 Q. My staff did not copy the part at the 10:55

14 back; okay? 10:55

15 A. Okay. 10:55

16 Q. So let me ask you some questions about 10:55

17 that. 10:55

18 It's in an e-mail; correct? 10:55

19 A. It is. 10:55

20 Q. Have you seen any evidence that that 10:55

21 tablet or card of tablets was returned to Actavis 10:55

22 or Mylan for analysis? 10:56

23 A. I have not seen any documentation that 10:56

24 shows that any chemical testing has been done on 10:56

25 any of the thick, thin, or whatever tablets. 10:56

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1 Q. I didn't ask about chemical testing. 10:56

2 All I did was ask if you've seen any documents to 10:56

3 indicate that that tablet or card of tablets was 10:56

4 returned to Actavis or Mylan. 10:56

5 A. This is the only reference that I've 10:56

6 seen with respect to these. 10:56

7 Q. And it contains no statement that the 10:56

8 tablet or tablets were returned to Actavis or 10:57

9 Mylan; correct? 10:57

10 A. This e-mail does not say that it was 10:57

11 returned. 10:57

12 Q. Was it in a blister pack? 10:57

13 A. It says the card had four tablets. 10:57

14 Q. Do you take that to mean blister pack? 10:58

15 A. I'm not sure. I'm not sure what it 10:58

16 means. 10:58

17 Q. Was it removed from the card or blister 10:58

18 pack? 10:58

19 A. It says here just that the remaining 10:58

20 tablets are in a blister pack -- not a blister 10:58

21 pack but a card. That's it. That's all that it 10:58

22 says. 10:58

23 Q. Do you know anything about the 10:58

24 manufacturer specifications of the card or blister 10:58

25 pack in which those tablets were? 10:58

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1 A. No, I don't know anything about those. 10:58

2 Q. So you don't know whether a blister pack 10:58

3 would even accommodate an extra thick tablet, do 10:58

4 you? 10:58

5 A. I'd have to go look at the documentation 10:59

6 because some of the documents I reviewed with 10:59

7 respect to UDL talks about that issue. 10:59

8 Q. And if this blister pack or card had 10:59

9 been made by UDL, a double-thick tablet couldn't 10:59

10 fit in it, could it? 10:59

11 A. I couldn't say. 10:59

12 Q. Do you remember what the specs were? 10:59

13 A. I don't remember the specs. 10:59

14 Q. Would a wise and prudent manufacturer 10:59

15 use so much raw materials of plastic and tinfoil 10:59

16 to accommodate more space than they needed in the 10:59

17 blister pack? 10:59

18 A. Could you say that again? 10:59

19 Q. Would a prudent manufacturer use more 10:59

20 plastic and tinfoil than needed to package the 10:59

21 tablets in a blister pack? 10:59

22 A. I don't think you can draw the 10:59

23 conclusion that a double tablet would not fit in a 10:59

24 blister pack. You just don't have enough 10:59

25 information to do that. 10:59

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1	Q.	You don't.	10:59
2	A.	No. I don't think anybody does from the	10:59
3		literature I've read.	11:00
4	Q.	Okay. Did anybody in that e-mail remove	11:00
5		a tablet and measure it with a micrometer?	11:00
6	A.	Not according to this e-mail. And	11:00
7		that's a really interesting point out of all of	11:00
8		this that's very striking when you look at all the	11:00
9		data.	11:00
10	Q.	You have to answer my question.	11:00
11		MR. KERENSKY: He just said he did.	11:00
12		MR. MORIARTY: I don't want a speech,	11:00
13		Mike. I want to know whether anybody	11:00
14		indicates that they removed it and measured it	11:00
15		with a micrometer, yes or no?	11:00
16		THE WITNESS: In this e-mail, no.	11:00
17		MR. KERENSKY: Wait a minute. Wait a	11:00
18		minute.	11:00
19		MR. MORIARTY: I'm going to let him make	11:00
20		his speech in minute; okay?	11:00
21		MR. KERENSKY: Let him finish his answer.	11:00
22		MR. MORIARTY: I want to ask my	11:00
23		questions.	11:00
24		MR. KERENSKY: Let him finish his	11:00
25		answer. Right now.	11:00

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1 MR. MORIARTY: He did. He said correct. 11:00

2 MR. KERENSKY: He did not. You 11:00

3 interrupted him right in the middle? 11:00

4 Q. Now if you -- 11:00

5 MR. KERENSKY: Stop. The deposition is 11:00

6 stopped. 11:00

7 MR. MORIARTY: You think you have the 11:00

8 authority to do that under PTL 22? 11:00

9 MR. KERENSKY: I think I do. I'll take 11:00

10 the chance. Are you going to let him finish 11:00

11 his answer? 11:00

12 BY MR. MORIARTY: 11:00

13 Q. Go ahead and finish your speech. 11:00

14 A. Speech? 11:00

15 Q. Yeah, go ahead. 11:00

16 A. I -- to tell you the truth -- because of 11:00

17 that exchange, I don't know where the question 11:00

18 was. 11:01

19 MR. KERENSKY: Okay. Let's go back up 11:01

20 and pick up where he interrupted you and then 11:01

21 you can finish your thought. You have the 11:01

22 right to do that. 11:01

23 (Whereupon, the testimony was read 11:01

24 back by the court reporter, as recorded above) 11:01

25 MR. KERENSKY: Finish your thought and 11:01

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1	then move on.	11:01
2	THE WITNESS: Yeah, it's been	11:01
3	demonstrated that a significant number -- when	11:01
4	you look at FDA findings and reports or	11:01
5	whatever -- of double-thick tablets that were	11:01
6	produced, nobody ever performed any testing on	11:01
7	those, according to the record that I can	11:01
8	find. Which is really unusual because we	11:01
9	don't know whether it's out of spec or in	11:01
10	spec, all the points that you are going to,	11:01
11	you just don't know because nobody apparently	11:02
12	did it. Or if they did it, they didn't report	11:02
13	it.	11:02
14	BY MR. MORIARTY:	11:02
15	Q. Are you done?	11:02
16	A. Yes, sir.	11:02
17	Q. So according to this e-mail, whatever	11:02
18	tablet or tablets those were -- first of all, it	11:02
19	only refers to one tablet doesn't it, in the	11:02
20	card? It doesn't say all four were double; right?	11:02
21	A. It says please be advised that Lynne	11:02
22	Farrell of CSC reports finding a card of Digoxin	11:02
23	with one double thick tablet at GL-Gloucester.	11:02
24	Q. What a CSC?	11:02
25	A. I don't know.	11:02



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1 Q. So you don't know anything about the 11:02  
2 reliability of this person who supposedly found 11:02  
3 this; correct? 11:02

4 A. It's an e-mail. It would be difficult 11:02  
5 to do that. 11:02

6 Q. All right. And certainly this was not 11:02  
7 in the hands or mouth of a consumer; correct? 11:02

8 A. This particular one right here? 11:02

9 Q. Right. 11:02

10 A. From the e-mail, that's the conclusion 11:02  
11 you could probably draw. 11:02

12 Q. If you were using the scientific method 11:02  
13 to figure out -- you're called in as a consultant 11:02  
14 to find out if double-thick tablets have actually 11:03  
15 made it to the hands of consumers and you're using 11:03  
16 the scientific method with data, this e-mail is 11:03  
17 not a particularly reliable report, is it? 11:03

18 MR. FITZPATRICK: Object to the form. 11:03

19 THE WITNESS: I wouldn't consider this a 11:03  
20 report. It's a statement in an e-mail. 11:03

21 BY MR. MORIARTY: 11:03

22 Q. So it's not reliable data for you as a 11:03  
23 scientist to conclude that that was in fact a 11:03  
24 double-thick tablet; is that correct? 11:03

25 A. I don't think that's correct. It's 11:03

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1 something that starts a formal investigation. 11:03

2 It's a piece of data. 11:03

3 Q. With no measurement and no removal from 11:03  
4 its packaging; correct? 11:03

5 A. Correct. But observation is one of the 11:04  
6 critical components to scientific experiment. And 11:04  
7 observations such as this are critical when you're 11:04  
8 conducting investigations. 11:04

9 Q. Have you ever tried to observe the 11:04  
10 thickness down to the millimeter of a tablet in a 11:04  
11 blister pack? 11:04

12 A. In a blister pack? 11:04

13 Q. Yeah. 11:04

14 A. Down to the millimeter? 11:04

15 Q. Yes, sir. That's how thin these tablets 11:04  
16 are, isn't it? 11:04

17 A. I forget what the spec is for 11:04  
18 thickness. Me, personally, looking a blister pack 11:04

19 -- 11:04

20 Q. Yes. 11:04

21 A. -- and trying to estimate what the 11:04  
22 thickness would be, no, I had no -- would have no 11:04  
23 desire or need to do that. You wouldn't estimate 11:04  
24 if you're trying to come up with a spec. You'd 11:04  
25 measure it. 11:04

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1 Q. So we started this line of questions 11:04

2 with you know what a double-thick tablet is or an 11:04

3 oversized tablet; correct? 11:04

4 A. As they're referring to it in this 11:04

5 deposition, yes. 11:05

6 Q. In any context in the pharmaceutical 11:05

7 industry if somebody said to you we have oversized 11:05

8 tablets or double-thick tablets, you know what 11:05

9 that is; right? 11:05

10 A. This is the first time that I've heard 11:05

11 reference in the industry to a double-thick 11:05

12 tablet. It's that unique a situation. 11:05

13 Q. Okay. Do you know how many recalls 11:05

14 there have been in the last 36 months for extra 11:05

15 thick tablets in the pharmaceutical industry? 11:05

16 A. I do not. 11:05

17 Q. And you know what a normal tablet with 11:05

18 too much active pharmaceutical ingredient is, 11:05

19 don't you? 11:05

20 A. I don't know if I understand the 11:05

21 question. You can't just look at a tablet and 11:05

22 know how much ingredient is in it. 11:05

23 Q. I didn't imply or ask you if you could. 11:05

24 But a normal-sized tablet could have too much 11:05

25 active pharmaceutical ingredient; correct? 11:05

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1 A. Yes. 11:05

2 Q. You could assay or content uniformity 11:05

3 test that tablet to determine that; correct? 11:05

4 A. Yes. 11:05

5 Q. Do you know enough about the 11:06

6 manufacturing process to say whether the root 11:06

7 cause of an extra thick is typically different 11:06

8 than the root cause of a normal size with too much 11:06

9 active pharmaceutical ingredient? 11:06

10 A. Say that again. 11:06

11 (Whereupon, the testimony was read back 11:06

12 by the court reporter, as recorded above) 11:06

13 THE WITNESS: Based on the information 11:06

14 and the data that I have here, Actavis 11:06

15 specifically indicated that there were 11:06

16 problems in the manufacturing of this product 11:06

17 very early on. It was very difficult. In 11:06

18 19-- whatever, 2000. And it took them a lot 11:06

19 to do it. And as they moved forward and they 11:07

20 had problems, they had problems with blend 11:07

21 uniformity and then obviously with 11:07

22 manufacturing the tablet and, therefore, it is 11:07

23 possible -- based on the information I looked 11:07

24 at -- that you could have both of those 11:07

25 problems because of difficulties with blend 11:07

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1 uniformity and with tableting. It's possible. 11:07

2 MR. MORIARTY: Motion to strike. It was 11:07

3 completely non-responsive to my question. 11:07

4 MR. KERENSKY: He has to do that for the 11:07

5 judge. 11:07

6 THE WITNESS: I understand. 11:07

7 MR. KERENSKY: That's fine. 11:07

8 BY MR. MORIARTY: 11:07

9 Q. I'm talking about manufacturing tablets 11:07

10 and whether you have any knowledge of whether 11:07

11 those two distinct problems in manufacturing have 11:07

12 different root causes. 11:07

13 A. In general? 11:07

14 Q. Yes. 11:07

15 A. Say that again, please. 11:08

16 Q. Okay. 11:08

17 A. Because it's a very broad statement. 11:08

18 Q. Let's get back to basics. 11:08

19 A. Okay. 11:08

20 Q. If somebody says you have extra thick or 11:08

21 double-thick tablets, that's a reference to size; 11:08

22 correct? 11:08

23 A. I would assume so, yes. 11:08

24 Q. All right. And that size could be 11:08

25 caused by too much active pharmaceutical 11:08

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1 ingredient, too much excipient, inadequate 11:08  
2 compression making a fluffy tablet, double 11:08  
3 compression, could be caused by any number of 11:08  
4 things; correct? 11:08

5 A. That's -- there are many things it could 11:08  
6 be, yes. 11:08

7 Q. All right. So a normal-sized tablet 11:08  
8 with too much active pharmaceutical ingredient is 11:08  
9 a different problem in the pharmaceutical 11:08  
10 manufacturing process, isn't it? 11:08

11 A. I don't think you can say that 11:09  
12 exclusively. I think that, you know, it's a 11:09  
13 manufacturing train, it's a process. And if you 11:09  
14 don't have control of your process, it's possible 11:09  
15 to have those two events as a failure in the 11:09  
16 process. 11:09

17 Q. I'm not asking whether you can only have 11:09  
18 one or the other. I'm asking whether they're 11:09  
19 different. And if a tablet is normal-sized, by 11:09  
20 definition it's not extra-thick or double-thick; 11:09  
21 correct? 11:09

22 A. Yes. 11:09

23 Q. So a normal-sized tablet with too much 11:09  
24 ABI, the problem is the amount of active 11:09  
25 pharmaceutical ingredient; correct? 11:09

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1 A. I'm not trying to be difficult. I'm 11:09  
2 just trying to understand the question here. I 11:09  
3 apologize. 11:09

4 Q. If I said to you -- 11:09

5 A. Uh-huh. 11:09

6 Q. -- Mr. Bliesner, I want you to come in 11:09  
7 and consult with my pharmaceutical manufacturing 11:10  
8 company. 11:10

9 A. Uh-huh. 11:10

10 Q. Our tablets are double-thick. 11:10

11 A. Uh-huh. 11:10

12 Q. And I tell you nothing more. 11:10

13 A. Uh-huh. 11:10

14 Q. The problem is a size problem to start 11:10  
15 with; correct? 11:10

16 A. Uh-huh. 11:10

17 Q. Is that a yes? 11:10

18 A. Double-thick, yes. 11:10

19 Q. All right. At some point you'd get to 11:10  
20 the issue of what the active pharmaceutical 11:10  
21 content of those tablets is if you were doing an 11:10  
22 investigation; correct? 11:10

23 A. Yes, it would be one of the first things 11:10  
24 you'd do. 11:10

25 Q. But if I told you that my problem was 11:10

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1 normal-sized tablets with too much API, the 11:10  
2 investigation process would be different, correct, 11:10  
3 because the problem is different. 11:10

4 A. Actually, no. 11:10

5 Q. All right. Well, the focus would be on 11:10  
6 why is there too much API; right? 11:10

7 A. I don't think you'd look at those things 11:10  
8 mutually exclusively. 11:10

9 Q. Do you think the FDA knows the 11:10  
10 difference between extra-thick tablets and tablets 11:10  
11 of normal size but too much Digoxin? 11:10

12 A. I'm sure they do. 11:11

13 Q. Have you seen the FDA approved press 11:11  
14 release for this recall? 11:11

15 A. I'm not sure. 11:11

16 Q. There you go. Exhibit 36. Have you 11:11  
17 seen this? 11:11

18 A. Yes, I have. 11:12

19 Q. Okay. It says: 11:12

20 "The voluntary all-out recall is due to the 11:12  
21 possibility that tablets with double the 11:12  
22 appropriate thickness may have been commercially 11:12  
23 released." 11:12

24 A. It does say that. 11:12

25 Q. And in this sentence, the words 11:12



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1 "possibility" and "may" are different than 11:12

2 "probability" "likely" and "certainty"; correct? 11:12

3 MR. KERENSKY: Objection, vague. 11:12

4 BY MR. MORIARTY: 11:12

5 Q. Is that right? 11:12

6 A. Again, we're back to the definition of 11:12

7 "probable" and "possible." 11:12

8 Q. Which you don't know the difference; 11:12

9 right? 11:12

10 A. In the context in this industry, as 11:12

11 having sat down and thought about it, like I said 11:12

12 before, no. 11:12

13 Q. Well, at least the sentence "FDA 11:12

14 approved" doesn't say that we know for a fact that 11:13

15 double-thick tablets were commercially released; 11:13

16 right? It doesn't say that. 11:13

17 A. It does not say that. However, I have 11:13

18 never seen a recall notice that says absolutely. 11:13

19 This is the way they're stated. 11:13

20 Q. And then it says these tablets may 11:13

21 contain twice the approved level of active 11:13

22 ingredient than is appropriate; correct? 11:13

23 A. It does say that. 11:13

24 Q. Have you seen any FDA document which 11:13

25 says that this recall was for normal-sized tablets 11:13

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1 with too much active pharmaceutical ingredient? 11:13

2 A. Recall document? 11:13

3 Q. Any document. Any -- 11:13

4 A. Any document? 11:13

5 Q. Any document from the FDA. 11:13

6 A. Say it again. Again -- 11:13

7 Q. Have you seen any -- 11:13

8 A. -- I'm not trying to be difficult. I 11:13

9 just want to make sure I answer your question 11:13

10 correctly. 11:13

11 Q. Have you seen any document from the 11:13

12 FDA -- whether it's a paper they promulgated, a 11:14

13 report, or a 483 warning letter, anything -- or 11:14

14 even their website -- to indicate that this recall 11:14

15 was for normal-sized tablets with too much 11:14

16 Digoxin. 11:14

17 A. Not that I recall. 11:14

18 Q. To your recollection, did the FDA ever 11:14

19 cite, warn, or observe that Digitek with normal 11:14

20 size but too much active pharmaceutical ingredient 11:14

21 had reached the marketplace? 11:14

22 A. Can I take a look real quick at my 11:15

23 report? 11:15

24 Q. Sure. 11:15

25 A. My notes and my report, I don't have any 11:18

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1 record of the FDA making a statement like that. 11:18

2 Q. Please look at Exhibit 38. Terry, I'll 11:18

3 give you a copy. 11:18

4 Do you know if you've ever seen this before, 11:18

5 Mr. Bliesner? 11:18

6 A. I think I may have. 11:18

7 Q. All right. Exhibit 38 is a printout 11:18

8 from the FDA's website. I believe this was posted 11:18

9 in July of 2009, a year and a quarter after the 11:18

10 recall. 11:18

11 Go to the second page, please. 11:19

12 A. Uh-huh. 11:19

13 Q. First of all, this is called Facts and 11:19

14 Myths About Generic Drugs; right? 11:19

15 A. Yes. 11:19

16 Q. And on the second page it says, "Myth, 11:19

17 there are quality problems with generic drug 11:19

18 manufacturing. A recent recall of generic 11:19

19 Digoxin -- called Digitek -- shows that generic 11:19

20 drugs put patients at risk." 11:19

21 Did I read that correctly? 11:19

22 A. Yes. 11:19

23 Q. And then it says, "Fact. FDA's 11:19

24 aggressive action in this case demonstrates the 11:19

25 high standards to which all prescription drugs -- 11:19

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1 generic and brand name -- are held"; correct? 11:19

2 A. Correct. 11:19

3 Q. All right. Let's go down to the third 11:19  
4 bullet point. 11:19

5 A. Yes. 11:19

6 Q. Well, actually, let's go to the second 11:19  
7 bullet point. Well, I'm sorry. Withdraw that. 11:20

8 Look at the first three bullet points. 11:20

9 A. Okay. 11:20

10 Q. All right. What they are describing in 11:20  
11 the first three bullet points is the incident in 11:20  
12 November, December, January 2007 to 2008 regarding 11:20  
13 batch 70924 with the 20 double-thick tablets; 11:20  
14 correct? 11:20

15 A. I don't know if that's the specific 11:20  
16 batch. I'd have to go back and look it up. 11:20

17 Q. Trust me. 11:20

18 A. Yeah. 11:20

19 Q. Okay. That's that they're talking 11:20  
20 about; right? 11:20

21 A. It appears. 11:20

22 Q. All right. So in the third bullet point 11:20  
23 it says: 11:20

24 "Although Actavis attempted to remove the 11:20  
25 affected Digitek through visual inspection, FDA 11:20

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1 determined that this method of removal was 11:20  
2 inadequate to assure the product quality and 11:20  
3 consistency in accordance with the current good 11:21  
4 manufacturing practice regulations"; correct? 11:21  
5 A. Sure. 11:21  
6 Q. So what they're referring to is an 11:21  
7 inspection issue; is that right? 11:21  
8 A. A visual inspection. 11:21  
9 Q. Yes. 11:21  
10 A. Correct. 11:21  
11 Q. Bullet point 4, second sentence: 11:21  
12 "In our best judgment, given the very small 11:21  
13 number of defective tablets that may have reached 11:21  
14 the market and the lack of reported adverse events 11:21  
15 before the recall, harm to patients was very 11:21  
16 unlikely." 11:21  
17 First of all, did I read it correctly? 11:21  
18 A. You read it as written. 11:21  
19 Q. Do you have some reason to disagree with 11:21  
20 the FDA's findings in this regard? 11:21  
21 A. Absolutely. 11:21  
22 Q. What's the basis for your disagreement 11:21  
23 with FDA? 11:21  
24 A. My disagreement with FDA, first of all, 11:21  
25 there's political overtones that are always 11:21

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1 associated with these statements reporting to the 11:21  
2 press at the FDA. And if you go back and look at 11:22  
3 the FDA's record over the course of, you know, the 11:22  
4 last 20 years if you will, approximately, go back 11:22  
5 and look at the timeline, the FDA has repeatedly 11:22  
6 found this company to be in significant violation 11:22  
7 of the GMPs. To my knowledge, this is only 11:22  
8 company that's ever been under consent decree 11:22  
9 twice. 11:22

10 Q. Are you done with your answer? 11:22

11 A. For now, yes. 11:22

12 Q. Okay. Can you explain to us all, 11:22  
13 please, what expertise you have in the political 11:22  
14 analysis of the FDA? 11:22

15 Can you explain that to me, please, what 11:23  
16 expertise you have from your background, training, 11:23  
17 and experience, that you can assess the political 11:23  
18 overtones or motivations of this statement on the 11:23  
19 website? 11:23

20 A. In my experience, recent experience, I 11:23  
21 see serious discussions that go on between two 11:23  
22 major branches within the FDA that are often in 11:23  
23 conflict with one another. Drug shortage, for 11:23  
24 instance, and compliance. And they are very 11:23  
25 politically motivated and their purpose is that 11:23

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1 their ends are -- end missions are different. 11:23

2 That's my experience of it. 11:24

3 Q. Is that a scientific opinion? 11:24

4 A. We're talking about politics. 11:24

5 Q. Okay. So what would be the political 11:24

6 motivation a year and a quarter after a recall for 11:24

7 them to say this about the number of defective 11:24

8 tablets that may have reached the market and the 11:24

9 level of risk to consumers? 11:24

10 A. Why would they say that? 11:24

11 Q. Yeah. What data do you have to say that 11:24

12 this is somehow politically motivated? What's 11:24

13 your -- what's your underlying data? 11:24

14 A. The underlying data is their 11:24

15 documentation in the establishment inspection 11:24

16 reports that shows gross violation of the GMPs 11:24

17 throughout the history of this company and that 11:24

18 they approved them after the first consent decree 11:24

19 as being okay and they ended up right back in the 11:24

20 same place. So I would be hard pressed to want to 11:24

21 admit in public that they may have potentially not 11:24

22 served their mission correctly after the first 11:25

23 consent decree. 11:25

24 Q. So if I understand what you're saying, 11:25

25 the FDA soft-pedaled this statement about the 11:25

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1 Digitek recall to deflect attention from their 11:25

2 lack of oversight for the company; is that right? 11:25

3 A. Politically it's a possibility. 11:25

4 Q. Is it a probability? 11:25

5 A. I don't -- I don't agree with that 11:25

6 statement. 11:25

7 Q. Is it a probability? 11:25

8 A. I couldn't go anywhere back to 11:25

9 possibility, probability either. 11:25

10 Q. Is it a certainty? 11:25

11 A. I don't know. We're talking politics 11:25

12 here, we're not talking science. We shifted from 11:25

13 science to politics. 11:25

14 Q. I didn't; you did. I'm asking whether 11:25

15 you have some data to support the opinion you're 11:25

16 now giving. 11:25

17 A. It's my opinion and it's a political 11:25

18 one. And there are no direct data other than the 11:25

19 FDA's voluminous EIR 483 inspections, warning 11:25

20 letters. 11:25

21 THE VIDEOGRAPHER: The time is . We 11:26

22 are going off the record briefly. 11:26

23 (Short break) 11:31

24 THE VIDEOGRAPHER: The time is now 11:31

25 11:32 a.m. We are back on the record. This 11:31



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1 is the beginning of tape three. 11:31

2 BY MR. MORIARTY: 11:31

3 Q. Mr. Bliesner, the -- or Dr. Bliesner I'm 11:31

4 sorry -- the -- I haven't asked you this in any 11:32

5 detail. I will get to it later. 11:32

6 I assume that your opinions in this case about 11:32

7 adulterated product are based on 483s; is that 11:32

8 correct? 11:32

9 A. Partially. 11:32

10 Q. And warning letters? 11:32

11 A. Partially. 11:32

12 Q. And establishment inspection reports? 11:32

13 A. Partially. 11:32

14 Q. Those are all FDA documents; correct? 11:32

15 A. Correct. 11:32

16 Q. And are they based on the fact that 11:32

17 there have been two consent decrees? 11:32

18 A. What's based on two consent? 11:32

19 Q. Your opinions. 11:32

20 A. Partially. 11:32

21 Q. Okay. And those are, although not FDA 11:32

22 documents, they're negotiated with the FDA; is 11:33

23 that correct? 11:33

24 A. Consent decree? 11:33

25 Q. Yeah. 11:33

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1 A. Yes. 11:33

2 Q. Okay. So what other documents besides 11:33

3 FDA documents are your opinions based on that my 11:33

4 client made adulterated Digitek, in general? 11:33

5 A. In general? 11:33

6 Q. Yeah. 11:33

7 A. E-mail communications within the 11:33

8 company. Responses to 483 warning letters. 11:33

9 Q. Anything else? 11:33

10 A. Investigations. 11:33

11 Q. Those are by the FDA; correct? 11:33

12 A. A. No, internal investigations. 11:33

13 (Interruption) 11:34

14 MR. MORIARTY: We can go off the record. 11:34

15 THE VIDEOGRAPHER: The time is now 11:34

16 11:33 a.m. We are going off the record. 11:34

17 (Short break) 11:35

18 THE VIDEOGRAPHER: The time is now 11:35

19 a.m. We are back on the record. 11:35

20 THE WITNESS: The Marine Corps kicked in 11:35

21 there for a second. 11:35

22 BY MR. MORIARTY: 11:35

23 Q. Have any of the companies that you 11:35

24 worked for in the pharmaceutical business or with 11:35

25 which you've consulted had recalls? 11:35

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1 A. Yes. 11:35

2 Q. Have there been recalls in your 11:35

3 experience where there was no actual proof that 11:35

4 there was out of specification, dangerous product 11:35

5 in the market? 11:35

6 A. I'm sorry. Still a bit distracted. 11:35

7 Please. 11:35

8 Q. Okay. In your experience, have there 11:35

9 been recalls of pharmaceutical product to the 11:35

10 consumer level where there was no actual proof 11:35

11 that there was out of specification, dangerous 11:36

12 product in the hands of consumers? 11:36

13 A. I can't think of a specific example. 11:36

14 Q. In general have there been? 11:36

15 A. Possibly. 11:36

16 Q. Okay. So, for example, there could be a 11:36

17 recall of a drug product because of a packaging 11:36

18 issue. The label might be on upside down; is that 11:36

19 right? 11:36

20 A. Correct. 11:36

21 Q. So the mere fact that there's a recall 11:36

22 does not in and of itself mean that the product is 11:36

23 out of spec and dangerous to the consumer; right? 11:36

24 A. That's correct. 11:36

25 Q. You want to know more about that if 11:36

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1 you're going to -- if you're going to determine 11:36  
2 whether it's actually out of spec and dangerous to 11:36  
3 consumers, you want to know more than just the 11:36  
4 fact that there was a recall; right? 11:36

5 A. Yes. 11:36

6 Q. Okay. Now, if the FDA says in effect 11:36  
7 that a product is adulterated, does that always 11:37  
8 lead to a recall? 11:37

9 A. No. 11:37

10 Q. Why not? 11:37

11 A. Numerous reasons it could be that way. 11:37

12 Q. Give me some, please. 11:37

13 A. Hasn't shipped is the first thing that 11:37  
14 comes to mind. 11:37

15 Q. Okay. 11:37

16 A. That would be the primary one. 11:37

17 Q. Any others? 11:37

18 A. No. But, I'm not an expert in recalls. 11:37

19 Q. Okay. Well, the FDA could determine 11:37  
20 that there is adulterated product and have a 11:37  
21 recall not to the consumer level also; correct? 11:37

22 A. As I understand, yes. 11:38

23 Q. In other words, the FDA in effect is 11:38  
24 making a determination that whatever product is 11:38  
25 being recalled isn't necessarily dangerous to the 11:38

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1 consumers; right? 11:38

2 A. A recall can be of something that isn't 11:38

3 necessarily an immediate danger as I understand 11:38

4 it, not being an expert in recalls. 11:38

5 Q. Okay. So I'm showing you Exhibit 39. 11:38

6 Have you ever seen that before? 11:38

7 A. I don't think so. 11:39

8 Q. All right. This is a printout from the 11:39

9 FDA's website. 11:39

10 A. Uh-huh. 11:39

11 Q. And it's entitled "Facts About Current 11:39

12 Good Manufacturing Practices"; correct? 11:39

13 A. It is titled that, yes. 11:39

14 Q. And the fourth bold section down, says: 11:39

15 "If a manufacturer is not following cGMPs, are 11:39

16 drug product safe for use; correct"? 11:39

17 A. It is. 11:39

18 Q. The first sentence reads, "If the 11:39

19 company is not complying with cGMP regulations, 11:39

20 any drug it makes is considered adulterated under 11:39

21 the law." 11:39

22 Did I read it correctly? 11:39

23 A. You did. 11:39

24 Q. Do you agree with it? 11:39

25 A. By definition, I would agree with that. 11:39

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1	Q.	The next sentence says:	11:39
2		"This kind of adulteration means that the	11:39
3		drugs was not manufactured under conditions that	11:40
4		complied with GMP, cGMP."	11:40
5		Did I read it correctly?	11:40
6	A.	You did.	11:40
7	Q.	Do you agree with that?	11:40
8	A.	By definition, yes.	11:40
9	Q.	The next sentence says:	11:40
10		"It does not mean that there is necessarily	11:40
11		something wrong with the drug."	11:40
12		Did I read it correctly?	11:40
13	A.	You did.	11:40
14	Q.	Do you agree with it?	11:40
15	A.	Something wrong with the drug? It's a	11:40
16		broad statement; but as it's written, I would	11:40
17		agree.	11:40
18	Q.	All right. So in other words, the fact	11:40
19		that a drug may be considered adulterated does not	11:40
20		necessarily mean that it is outside its	11:40
21		specifications; right?	11:40
22	A.	Yes.	11:40
23	Q.	Because a drug could be adulterated for	11:40
24		a lot of different reasons having nothing to do	11:40
25		with the potency of the drug; right?	11:40

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1	A.	Correct.	11:40
2	Q.	Do you know how many batches of Digitek	11:41
3		were involved in the recall in 2008?	11:41
4	A.	Off the top of my head, no.	11:41
5	Q.	How many batch records did you look at?	11:41
6	A.	For?	11:41
7	Q.	Digitek.	11:41
8	A.	I looked at the batch records during the	11:41
9		ANDA, and I don't recall the number that were in	11:41
10		there.	11:42
11	Q.	Is that all?	11:42
12	A.	I'd have to check. Do you want me to	11:42
13		take the time to do that?	11:42
14	Q.	Well, let me ask you this: Did you look	11:42
15		at the batch that was involved in the double-thick	11:42
16		investigation in 2007 and 8? Did you look at the	11:42
17		batch record, I should say.	11:42
18	A.	I looked -- I'm pretty sure I've looked	11:42
19		at the investigation. And how much the batch	11:42
20		record was part of that, I'm not sure. I'm pretty	11:42
21		sure I looked at that investigation.	11:42
22	Q.	But you're not sure if you've ever	11:42
23		looked at that entire batch record?	11:42
24	A.	No.	11:42
25	Q.	And other than --	11:42

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1 A. No. 11:42

2 Q. -- what was in the ANDA, you can't tell 11:42

3 me that you looked at any other Digitek batch 11:42

4 records? 11:43

5 A. No, I haven't. 11:43

6 Q. All right. Do you know how many tablets 11:43

7 would have been involved in the Digitek recall? 11:43

8 A. Since I don't know how many batches 11:43

9 there were and what the exact number without 11:43

10 looking at it is, I couldn't tell you. 11:43

11 Q. All right. Do you know how many other 11:43

12 recall batches were of the dose level of .125? 11:43

13 A. Again, the same answer. I don't 11:43

14 remember the batches there were without 11:43

15 referring -- knowing how many tablets per batch, 11:43

16 what they would be. 11:43

17 Q. Do you have an opinion to a reasonable 11:43

18 degree of probability -- in other words, more 11:43

19 likely than not. 11:43

20 A. Probability more likely than not? 11:43

21 Q. How many of the Digitek tablets that 11:43

22 were recalled were outside their size 11:43

23 specifications? 11:44

24 A. Okay. 11:44

25 Q. Are you writing on an Exhibit? 11:44



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1	A.	Oh.	11:44
2	Q.	A marked Exhibit?	11:44
3	A.	Yes. I'm sorry. That's my notes.	11:44
4		MR. KERENSKY: Maybe we should put the	11:44
5		pen away.	11:44
6		THE WITNESS: Take them away from me.	11:44
7		Sorry.	11:44
8		MR. MORIARTY: Kind of like guns. The	11:44
9		problem is the pen, not the paper; okay.	11:44
10		BY MR. MORIARTY:	11:44
11	Q.	Do you remember my question? Do you	11:44
12		remember my question?	11:44
13	A.	No, I don't remember.	11:44
14	Q.	Do you have an opinion to a reasonable	11:44
15		degree of probability how many of the recalled	11:44
16		Digitex tablets were outside their size	11:44
17		specifications?	11:44
18	A.	The recalled batches in the total	11:44
19		number?	11:44
20	Q.	Yeah.	11:44
21	A.	Since I don't know how many are out	11:44
22		there, there's no way in the world that I could	11:44
23		estimate that.	11:44
24	Q.	Do you have an opinion to a probability	11:44
25		of how many recalled Digitex tablets were outside	11:44

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1 their United States pharmacopeia specifications 11:45

2 for active pharmaceutical ingredient? 11:45

3 A. In my opinion, I don't think there's 11:45

4 enough information for anybody to determine that. 11:45

5 Q. Now, have you ever seen a report of a 11:45

6 Digitek tablet from a Plaintiff in this litigation 11:45

7 that was outside its size specifications? 11:45

8 A. Say that again, please. 11:45

9 Q. Sure. In the course of your work -- 11:45

10 A. Yes. 11:45

11 Q. -- to prepare for this report -- 11:45

12 A. Yes. 11:45

13 Q. -- for today's deposition -- 11:45

14 A. Yes. 11:46

15 Q. -- have you seen either a tablet or the 11:46

16 report of a tablet from a Plaintiff in the 11:46

17 litigation that says that that tablet was outside 11:46

18 its size specifications? 11:46

19 A. I would need to check the report again 11:46

20 to make sure. 11:46

21 Q. You can, but I guarantee you there was 11:46

22 no discussion of such thing in your report. But 11:46

23 if you'd like to check, you go right ahead. 11:46

24 A. I would. 11:46

25 Q. While you're looking, I want you to also 11:46

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1 look to see whether you have any report from a 11:46  
2 Plaintiff in this litigation of a Digitek tablet 11:46  
3 that was normal in size but had too much active 11:46  
4 pharmaceutical ingredient; okay? 11:46  
5 A. Uh-huh. Sure. 11:46  
6 Q. Are you done? 11:50  
7 A. Yes. Plaintiff, again, is the people 11:50  
8 bringing the lawsuit? 11:50  
9 Q. Yeah. 11:50  
10 A. No, I don't have any reference in any 11:50  
11 report. 11:50  
12 Q. Okay. How often do you look at the 11:50  
13 FDA's website in your work? 11:50  
14 A. Daily. 11:50  
15 Q. What would be a common source of 11:50  
16 reference for you? 11:50  
17 A. The source of references has to do with 11:50  
18 recall notice, Cedar newsletter, 483 reading, that 11:50  
19 kind of thing. 11:51  
20 Q. So you rely on the information in the 11:51  
21 FDA website for part of your day-to-day work in 11:51  
22 your consulting business? 11:51  
23 A. I rely on it to see what the trends are 11:51  
24 with respect to compliance enforcement and to use 11:51  
25 examples for my clients of what not to do. 11:51

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1 Q. If a company was consistently 11:51

2 manufacturing a drug with too much active 11:51

3 pharmaceutical ingredient in it; okay? 11:51

4 A. Okay. 11:51

5 Q. Would that likely be reflected in the 11:51

6 inventory usage cards? 11:51

7 A. When you say inventory usage cards, what 11:51

8 are you calling inventory usage cards? 11:51

9 Q. Do you know what inventory usage cards 11:52

10 are? 11:52

11 A. I've never heard that term. 11:52

12 Q. In your experience do your clients and 11:52

13 did the companies for which you worked keep 11:52

14 documentation of their inventory of raw materials? 11:52

15 A. Oh, absolutely, yes. 11:52

16 Q. So they could calculate how often they 11:52

17 needed to buy new material; correct? 11:52

18 A. That's true. 11:52

19 Q. And whether their usage of those raw 11:52

20 materials was consistent with the number of 11:52

21 batches that they were producing; right? 11:52

22 A. That's correct. It's part of the 11:52

23 control of the materials. 11:52

24 Q. So if a company hypothetically was 11:52

25 consistently producing a drug with too much active 11:52

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1 pharmaceutical ingredient, would it likely be 11:52  
2 somehow reflected in the inventory documentation 11:52  
3 for the active pharmaceutical ingredient at that 11:52  
4 company? 11:52

5 A. Not necessarily. 11:52

6 Q. Why not? 11:53

7 A. If you have blend uniformity problems 11:53  
8 for instance, you could be making sub-potent and 11:53  
9 super-potent tablets all at the same time and that 11:53  
10 would never reflect in an actual reconciliation 11:53  
11 with your raw materials. There wouldn't be a 11:53  
12 difference. 11:53

13 Q. Did FDA ever cite, warn, or observe that 11:53  
14 Actavis was making Digitek with batches that had 11:53  
15 super- and sub-potent tablets in it? 11:53

16 A. Did they ever -- say that again, please. 11:53

17 Q. Cite, warn, observe. In other words, 11:53  
18 did you see a warning letter, an EIR, or a 483, 11:53  
19 some statement from FDA that Digitek had batches 11:53  
20 with super- and sub-potent Digitek in it? 11:53

21 A. They make reference to thick and thin 11:53  
22 tablets, but I don't recall specifically if 11:53  
23 they -- that's associated with super or 11:53  
24 sub-potent. 11:54

25 Q. Okay. If a company was consistently 11:54

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1 manufacturing tablets with too much active 11:54

2 pharmaceutical ingredients, is it likely that that 11:54

3 would be detected at the blend uniformity stage? 11:54

4 A. If you've got problems with blend 11:54

5 uniformity, it's going to be picked up on testing. 11:54

6 Q. Okay. Now -- and if a company was 11:54

7 consistently manufacturing a pharmaceutical 11:54

8 product with too much active pharmaceutical 11:54

9 ingredient, isn't it likely that that would be 11:54

10 detected on finished product testing? 11:54

11 A. Yes. 11:54

12 Q. Can you show me anything in a batch 11:54

13 record or an FDA record to indicate that there was 11:54

14 a problem with Digitek having finished product 11:54

15 testing of out of spec Digitek with too much 11:54

16 active pharmaceutical ingredient in it? 11:55

17 A. FDA or Actavis both? 11:55

18 Q. Let's start with FDA. 11:55

19 A. Okay. There's reference to difficulties 11:55

20 on content uniformity testing. 11:55

21 Q. With Digitek? 11:55

22 A. Content uniformity in general if I'm not 11:55

23 mistaken, yes. 11:55

24 Q. I want to know about Digitek. 11:55

25 A. Uh-huh. 11:55

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1 Q. We're here about Digitek. These people 11:55  
2 represent people who took Digitek. 11:55

3 A. Uh-huh. There are documents with 11:55  
4 respect to content uniformity issues. 11:55

5 Q. Show me a document from the FDA or quite 11:55  
6 frankly even from Actavis to indicate that there 11:55  
7 were content uniformity problems with Digitek in 11:55  
8 2005, 6, 7 or 8. 11:55

9 A. This could take a while just so you 11:56  
10 know. 11:56

11 Q. Well -- 11:56

12 A. I've looked at thousands and thousands 11:56  
13 of pages of information. And to answer a specific 11:56  
14 question accurately and precisely, it's a 11:56  
15 non-trivial thing. 11:56

16 Q. Okay. Take your time. I want to know 11:56  
17 what documents you have in all this material to 11:56  
18 indicate that FDA or Actavis was having an 11:56  
19 out-of-specification finished product testing with 11:56  
20 Digitek in 2005, 6, 7 or 8? 11:56

21 A. Content uniformity, yes, with respect to 11:56  
22 blend. 11:56

23 Q. Or assay. I'm talking about finished 11:56  
24 product -- 11:56

25 A. Finished product. 11:56

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1 Q. -- testing? 11:57

2 A. No. In finished product, no. I'm 11:57

3 sorry. I misunderstood you because there are 11:57

4 issues with respect to blend uniformity; okay. 11:57

5 Nobody has ever tested the tablets that were 11:57

6 in question. Nobody that I know of. 11:57

7 Q. Nobody that you know of? 11:57

8 A. Not that I know of. 11:57

9 Q. Okay. 11:57

10 A. Which is strange in itself. 11:57

11 Q. Wouldn't it be required that Actavis 11:57

12 test every batch for assay, content uniformity, 11:57

13 dissolution, and then later certain batches tested 11:57

14 on stability? 11:57

15 A. Absolutely. And they would also be 11:57

16 expected to test those tablets that were found to 11:57

17 be double. 11:57

18 Q. I'm not asking you that. 11:57

19 A. Okay. 11:57

20 Q. So let's assume there were 152 recalled 11:57

21 batches, okay, that made it to market. 11:57

22 A. Uh-huh. 11:57

23 Q. Isn't it reasonable to assume that the 11:57

24 batch records for those 152 batches have finished 11:57

25 product testing data in them? 11:57



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1	A.	That is true.	11:58
2	Q.	Which you have not read; correct?	11:58
3	A.	Finished product testing for it?	11:58
4	Q.	Right; correct?	11:58
5	A.	I -- I can't say for sure I have not	11:58
6		seen some of the finished product testing results.	11:58
7	Q.	Well --	11:58
8	A.	Because I have looked at some notebooks	11:58
9		and I don't recall whether they are specifically	11:58
10		related to finished product testing.	11:58
11	Q.	Do you know as you sit here today	11:58
12		whether Actavis had out-of-spec finished product	11:58
13		test results with Digitek for any of the 152	11:58
14		recalled batches?	11:58
15	A.	I have not seen any released testing	11:59
16		data --	11:59
17	Q.	Okay.	11:59
18	A.	-- that supports that.	11:59
19	Q.	Do you know how many of the Plaintiffs	11:59
20		in this litigation have had their tablets tested	11:59
21		by independent labs?	11:59
22	A.	No idea.	11:59
23	Q.	Do you know of any out-of-spec tested by	11:59
24		Plaintiffs?	11:59
25	A.	I have no idea.	11:59

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1 Q. Did Mr. -- 11:59

2 A. I haven't been involved with the 11:59

3 Plaintiff. 11:59

4 Q. Did Mr. Kilpatrick who was here with you 11:59

5 yesterday and today tell you that they tested some 11:59

6 of their clients' tablets at NMS labs in 11:59

7 Philadelphia and they were within spec? 11:59

8 A. No. 11:59

9 Q. Do you know how many tablets were tested 11:59

10 by FDA under the 484 program with Digitek? 11:59

11 A. The number, no. 11:59

12 Q. Or how many batches? 11:59

13 A. Not off the top of my head, no. 11:59

14 Q. So when you said nobody tested, that's 11:59

15 not correct. 11:59

16 A. Right. I disagree with that statement. 11:59

17 Nobody tested the known double-thick that came up 11:59

18 during investigations. 11:59

19 Q. The 20. 12:00

20 A. No, the 1,300 and others that were 12:00

21 identified throughout the course of 12:00

22 manufacturing. It's been found several times that 12:00

23 the double-thick has showed up. 12:00

24 Q. Yeah, but did they ever make it to 12:00

25 consumers? 12:00

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1 A. Not that I know of, but they were never 12:00  
2 tested as part of the investigation. 12:00

3 Q. I understand. 12:00

4 A. Okay. 12:00

5 Q. But from time to time pharmaceutical 12:00  
6 companies are going to reject batches; is that 12:00  
7 right? 12:00

8 A. That's correct. 12:00

9 Q. Or parts of batches because they're out 12:00  
10 of spec in some way; right? 12:00

11 A. Parts of batches if they have a 12:00  
12 pre-approved protocol that allows for stuff like 12:00  
13 that. 12:00

14 Q. So Actavis could make a batch of 12:00  
15 Digitek, find that all or part of them were out of 12:00  
16 spec, and reject the batch; correct? 12:00

17 A. They could, yes. 12:00

18 Q. That's the way it's supposed to work; 12:00  
19 right? 12:00

20 A. Yes, it is. 12:00

21 Q. So let's talk about -- oh, by the way, 12:00  
22 while we're talking about testing, do most 12:01  
23 pharmaceutical manufacturers conduct in-process 12:01  
24 testing of size, weight, and hardness? 12:01

25 A. Tableting? 12:01

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1	Q.	Yes, in tableting.	12:01
2	A.	In my experience, yes.	12:01
3	Q.	So when they are checking, do they also	12:01
4		perform visual inspections for color and black	12:01
5		dots and anything else?	12:01
6	A.	For in-process?	12:01
7	Q.	Yeah.	12:01
8	A.	I think that depends on the individual	12:01
9		process being manufactured.	12:01
10	Q.	Well, to some degree when you're looking	12:01
11		at --	12:01
12	A.	Finished product, yes.	12:01
13	Q.	Okay. When you're looking at in-process	12:01
14		pharmaceutical, some of that involves power of	12:01
15		observation; correct?	12:01
16	A.	Yes.	12:01
17	Q.	Now, if -- oh, by the way, a minute ago	12:01
18		you said something about 1,300 extra thick. What	12:02
19		batches, what documents, what are you talking	12:02
20		about? Where do you get that number?	12:02
21	A.	I may have misspoke on exactly that, but	12:02
22		there is a citation in one of the EIRs with	12:02
23		respect to sampling of 1,300.	12:02
24	Q.	Do you know which EIR?	12:02
25	A.	I'm looking at the 483s.	12:02

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1 Q. I'll tell you what. Why don't we go on 12:03  
2 to a different topic? At the lunch break, I would 12:03  
3 like you to find the EIR or 483 that refers to 12:03  
4 that? 12:03

5 A. That refers to 1,300? 12:03

6 Q. Yes. 12:03

7 A. Sure. 12:03

8 Q. I'll write a note for you. 12:03

9 A. Okay. 12:04

10 Q. Okay. Let's assume that a customer 12:04  
11 called you in for a consulting arrangement and 12:04  
12 they told you that they wanted to find out 12:04  
13 whether -- they had made some double-thick tablets 12:04  
14 and they were interested in trying to figure out 12:04  
15 whether they had actually made it out of the plant 12:04  
16 to the distributor and all the way down to the 12:04  
17 consumer level; okay? 12:04

18 A. Okay. 12:04

19 Q. Now, in order to figure that out -- 12:04

20 A. Yes. 12:04

21 Q. -- would you want to look at finished 12:04  
22 product test data? 12:04

23 A. If I was going to solve that problem, I 12:04  
24 would. 12:05

25 Q. No, please listen. I'm not asking you 12:05

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1 to solve a manufacturing problem of double-thick 12:05

2 tablets. 12:05

3 A. Right. 12:05

4 Q. The inquiry is we just don't know -- 12:05

5 A. Right. 12:05

6 Q. -- and don't have the time to figure out 12:05

7 whether -- 12:05

8 A. Right. 12:05

9 Q. -- these actually got to consumers. 12:05

10 A. Right, right. My point being is that as 12:05

11 I said before, I'm not a recall expert. So I 12:05

12 would source somebody in my consulting chain who 12:05

13 is an expert in investigating products on the 12:05

14 market that may be adulterated and has done 12:05

15 recalls. I would not do -- undertake that 12:05

16 myself. It's not my expertise. It's a different 12:05

17 area altogether. 12:05

18 Q. Why is it a different area altogether? 12:05

19 A. It -- the whole concept of recall is 12:05

20 very complex and involves all kinds of different 12:05

21 outside agencies and coordinations. In fact, 12:05

22 these companies actually hire people to do recalls 12:05

23 themselves. Not themselves. They hire these 12:05

24 places. Stericycle I believe is the one that was 12:06

25 involved in helping out with this one. They go to 12:06

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1 the outside. It's a unique set of skills. 12:06

2 Q. Okay. But the company that's consulting 12:06

3 here isn't necessarily conducting a recall. 12:06

4 They're just trying to figure out -- 12:06

5 A. Whether -- 12:06

6 Q. -- whether it's a problem and maybe 12:06

7 whether they should recall. Do you still farm 12:06

8 that out? Sorry for the colloquialism. Do you 12:06

9 still subcontract that to somebody else in your 12:06

10 consulting chain? 12:06

11 A. Again, if it's specifically looking at 12:06

12 the impact, is stuff out on the market? 12:06

13 Q. Yeah. 12:06

14 A. Yeah, I would seek additional expertise. 12:06

15 Q. Okay. And why is that not part of your 12:06

16 expertise? 12:06

17 A. The -- as you know from the readings, 12:06

18 the whole concept of GMPs and quality systems 12:06

19 encompass several major categories, and I don't 12:07

20 know of anybody personally that understands all of 12:07

21 those main quality system elements, and that has a 12:07

22 tendency quite honestly to fall to a regulatory, 12:07

23 which is even outside the main quality systems. 12:07

24 Q. So as part of your investigation in this 12:07

25 case and your opinions in this case, in order to 12:07

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1 be consistent with your expertise, you would leave 12:07

2 it to other experts to determine if 12:07

3 out-of-specification Digitek made it to the 12:07

4 market, and if so, how much; is that right? 12:07

5 A. If it made it to the market and how 12:08

6 much. It wouldn't be binary -- you do it on or 12:08

7 off if you will; okay? Hand it off. It would be 12:08

8 something that I would be involved with from here 12:08

9 are the data that suggests or show that 12:08

10 adulterated product. 12:08

11 Q. Was made? 12:08

12 A. Was made. 12:08

13 Q. Right. 12:08

14 A. And could have potentially made it to 12:08

15 the market. Then you do the handoff to the people 12:08

16 that go out and try to assess that. 12:08

17 Q. Okay. So what you're really -- the core 12:08

18 of your expertise and the core of your report is 12:08

19 to analyze whether adulterated product was made -- 12:08

20 the first half of the equation you just talked 12:09

21 about; right? 12:09

22 A. And potentially made it to market. 12:09

23 Q. Right. 12:09

24 A. Uh-huh. 12:09

25 Q. Potentially, possibly. 12:09



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1	A.	Uh-huh.	12:09
2	Q.	Right? Am I right?	12:09
3	A.	Uh-huh.	12:09
4	Q.	That's a yes?	12:09
5	A.	Yes, I'm sorry. I keep forgetting it's	12:09
6		not just you and I having the conversation.	12:09
7	Q.	Look at page 7 of your report, please.	12:09
8		And I think we're using 92, Exhibit 92.	12:09
9	A.	Got you.	12:09
10	Q.	Got it?	12:09
11	A.	Yeah.	12:09
12	Q.	In the product recall section, on the	12:09
13		right-hand side, the third one down says 2008	12:10
14		Class I Digoxin, double-thick or super-potent;	12:10
15		okay?	12:10
16	A.	Yes.	12:10
17	Q.	Are you saying there normal size but too	12:10
18		much active pharmaceutical ingredient? Is that	12:10
19		what you mean by super-potent?	12:10
20	A.	Yes.	12:10
21	Q.	All right. So where in the FDA	12:10
22		documents does it say anything about the April	12:10
23		2008 recall being about normal size but too much	12:11
24		active pharmaceutical ingredient, super-potent	12:11
25		Digitex?	12:11

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1 A. In the FDA documentation? 12:11

2 Q. Correct, correct. 12:11

3 A. I don't believe there is anything in the 12:11  
4 FDA documentation after we talked about it. 12:11

5 Q. All right. 12:11

6 A. There is a statement in one of the 12:11  
7 original responses or drafts of the recall notice, 12:11  
8 if I remember, that they referred to overweight 12:11  
9 tablets which would imply super-potent. 12:11

10 Q. Overweight is a size issue, isn't it? 12:11  
11 Could have too many excipients in it, overweight? 12:11

12 A. It could be super-potent or sub-potent. 12:11

13 Q. Either one. 12:11

14 A. Because of blend uniformity issues that 12:11  
15 we talked about. 12:11

16 Q. It could be overweight and still have 12:11  
17 the right balance of pharmaceutical -- active 12:11  
18 pharmaceutical ingredient, couldn't it? 12:12

19 A. Balance? What do you mean by balance? 12:12

20 Q. Ratio. I mean in other words it could 12:12  
21 still be within the API specs and be overweight 12:12  
22 for some reason; right? 12:12

23 A. A dosage form is specific -- as you know 12:12  
24 is composed of actives and excipients and those 12:12  
25 ratios are very important. And not having that 12:12

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1 proper ratio and dosage form can cause 12:12

2 difficulties. 12:12

3 Q. Okay -- 12:12

4 A. In my experience. 12:12

5 MR. MORIARTY: Mike, Meghan, Terry, 12:12

6 whoever, I'm going to start using my favorite 12:13

7 documents, the 484s; okay? These are the ones 12:13

8 I told you I was not bringing an extra set of 12:13

9 because I had given them to everybody last 12:13

10 week; okay? 12:13

11 MR. KERENSKY: Sure. 12:13

12 BY MR. MORIARTY: 12:13

13 Q. I'm showing you Exhibit 24. I'll 12:13

14 represent to you that that is an FDA form 484 for 12:13

15 Digitek. 12:13

16 A. Uh-huh. 12:13

17 Q. Have you ever seen it? 12:13

18 A. Miss Johnson gave me some documents the 12:13

19 other day with respect to this type of thing. I 12:13

20 could have looked at this. 12:13

21 Q. Is that the first time you had seen the 12:13

22 484s? 12:13

23 A. Yes. 12:13

24 Q. So did you have a chance to go through 12:14

25 all of them? 12:14

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1 A. I did scan through them. 12:14

2 Q. All right. 12:14

3 A. Yes. 12:14

4 Q. So, for example, Exhibit 24 was Digitek 12:14

5 collected in February of 2007 by the FDA. 12:14

6 A. Uh-huh. 12:14

7 Q. Is that right? I mean that's who 12:14

8 collected 484 samples; right? 12:14

9 A. I'll tell you I'm not an expert in the 12:14

10 FDA's 484 and monitoring system. In fact I know 12:14

11 very few people who really are experts in that. 12:14

12 So this is my first exposure to the 484 program. 12:14

13 Q. Let me represent to you in February of 12:15

14 2007, FDA collected 200 count bottles of Digitek. 12:15

15 A. Uh-huh. 12:15

16 Q. It had to -- it came from batch 12:15

17 70078(a)(1). 12:15

18 A. Uh-huh. 12:15

19 Q. And FDA ran the tests that are described 12:15

20 in Exhibit 24 and the Digitek passed all the tests 12:15

21 to which it was subjected; okay? 12:15

22 A. Met the specification. 12:15

23 Q. Yes, met the specs. 12:15

24 First of all, do you have any reason to 12:15

25 disagree with me on that? 12:15

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1 A. No. 12:15

2 Q. Okay. Is it significant to you at all? 12:15

3 A. Significant? 12:15

4 Q. Yeah, is it significant in your analysis 12:15

5 of these cases that the FDA came in, tested the 12:15

6 product, sampled the product -- 12:16

7 A. Right. 12:16

8 Q. -- tested it. 12:16

9 A. Right. 12:16

10 Q. And it passed? 12:16

11 A. Right. I will tell you this: When I 12:16

12 first looked through here, I went oh, Jeez they 12:16

13 passed all the specs except for a few things in 12:16

14 here that are bit odd that I'm surprised nobody 12:16

15 picked up. For instance, some chromatography is 12:16

16 particularly ugly, which would lend problems. 12:16

17 Dissolution is a strange method that it's always 12:16

18 higher than the assay, which is problematic from a 12:16

19 scientific standpoint. 12:16

20 But in the end, when you look at the values, 12:16

21 it appears that they ran the assays and they met 12:16

22 the spec. Then when I stopped and thought about 12:16

23 it, it's like it doesn't really mean anything 12:16

24 because nobody is testing products that were 12:16

25 double-thick. You would expect to get decent 12:16

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1 readings, results, for the most part. 12:16

2 Q. Why would you expect to get decent 12:16

3 results for the most part? 12:16

4 A. Well, the link being that, you know, 12:16

5 overweight or large tablets would imply that 12:16

6 there's -- there's something wrong with the dosage 12:16

7 and it would show up on assay, but nobody ever 12:17

8 analyzed any of those. 12:17

9 Q. Okay. So -- so did you conclude that if 12:17

10 the tablets weren't double-thick, they would most 12:17

11 likely meet their specifications if tested like 12:17

12 this? 12:17

13 MR. KERENSKY: Object as to form. 12:17

14 THE WITNESS: As talked about before, 12:17

15 it's a possibility that you could have a 12:17

16 tablet that isn't double-thick or super-potent 12:17

17 because of blend uniformity problems. All you 12:17

18 can say is that the product that they tested 12:17

19 here in the surveillance passed the spec. 12:17

20 That's all -- that's all you can conclude out 12:17

21 of it. 12:17

22 BY MR. MORIARTY: 12:17

23 Q. All right? 12:17

24 A. Nothing more. 12:17

25 Q. And they had the opportunity to test as 12:17

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1 much as they wanted at that time; correct? 12:17

2 A. I don't know if that's a fair statement, 12:17

3 as much as they wanted. They did random 12:17

4 sampling. From what I understand, again I've just 12:18

5 recently been exposed to this program that it's a 12:18

6 random sampling, statistical sampling, and it is 12:18

7 in a lot of product. 12:18

8 Q. Well, they could have -- they could have 12:18

9 tested all 200 of the tablets that they secured; 12:18

10 correct? 12:18

11 A. They could have, but they didn't. 12:18

12 Q. Right. 12:18

13 A. Which is problematic if you're looking 12:18

14 for specific things, so... 12:18

15 Q. Do you assume that the FDA visually 12:18

16 inspected the 200 tablets that they did take 12:18

17 before they chose the ones to chemically test? 12:18

18 A. If their methods say they did, then they 12:18

19 did. I'm not sure what's in here as far as the 12:18

20 method goes. You realize that an analytical 12:18

21 method, if it's for assay, people if they're in a 12:18

22 hurry in particular don't necessarily take a look 12:18

23 at the dosage forms. 12:18

24 If the spec says, visual -- you know, I forget 12:18

25 the term right off the top of my head now, you 12:19

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1 know, description. Then they sit down and they'll 12:19

2 do a description and purposely look at it. 12:19

3 It's a problem when you're in a high-volume 12:19

4 laboratory of people not actually looking at the 12:19

5 dosage form and doing the test. I've had problems 12:19

6 with it in my own people. 12:19

7 Q. Do you know anything about how 12:19

8 high-volume the 484 program is? 12:19

9 A. No. 12:19

10 Q. And you don't know how carefully they 12:19

11 looked at these tablets for size, weight, overall 12:19

12 -- 12:19

13 A. I don't have -- 12:19

14 Q. -- aside from the ones they tested. 12:19

15 A. I don't have their methods, I don't have 12:19

16 their notebooks, and I'm not in their facility. 12:19

17 Q. All right. 12:19

18 So Exhibit 25, had you ever seen this 484 12:19

19 before the other day? 12:19

20 A. I didn't see any 484-related 12:19

21 documentations prior to the other day. 12:19

22 Q. All right. So this is another instance 12:19

23 where the FDA went out, sampled Digitek, tested it 12:19

24 in whatever manner they did, and found it to be 12:20

25 within compliance with the specs. 12:20



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1 Do you have any reason to disagree with that? 12:20

2 A. If that's what the document says, I -- 12:20

3 no. 12:20

4 Q. Okay. Do you think it's significant 12:20

5 that FDA once again found Digitek within specs 12:20

6 when they tested it? 12:20

7 A. No, I don't. When you look at the sheer 12:20

8 number of tablets that have been produced here, a 12:20

9 random sampling of certain lots at certain times 12:20

10 doesn't necessarily show you that there's bad 12:20

11 product out or not bad product out on the market. 12:20

12 Q. And it doesn't show you that there is; 12:20

13 correct? 12:20

14 A. I agree. 12:20

15 Q. All right. Had you seen Exhibit 26 12:20

16 before the other day? 12:20

17 A. Same thing. This is part of a 484. 12:20

18 Q. So once again it's FDA testing of 12:20

19 Digitek, finding it to be within compliance. Do 12:20

20 you think that's significant? 12:20

21 A. Finding the samples they tested to be 12:20

22 within compliance? 12:20

23 Q. Correct. 12:20

24 A. Uh-huh. 12:20

25 Q. Is it significant? 12:20

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1           A.       Again, the point being if this is not           12:21  
2   a -- nobody's ever tested -- we wouldn't even be           12:21  
3   having this conversation if somebody had taken the           12:21  
4   tablets that they found that were thick or thin           12:21  
5   and tested them and proved it wasn't a problem           12:21  
6   because then you'd know for sure that that -- that           12:21  
7   it's a problem. And nobody's done that. That's           12:21  
8   what really nagged at me through this whole thing.           12:21  
9           Q.       Does it nag at you at all that nobody in           12:21  
10   the course of your engagement in this has shown           12:21  
11   you a double-thick tablet that was actually in the           12:21  
12   hands of a consumer?           12:21  
13           A.       Yeah, I'm not sure --           12:21  
14                   MR. MORIARTY: Read that back.           12:21  
15                   THE WITNESS: Yes, please.           12:21  
16                   (Whereupon, the testimony was read back           12:22  
17   by the court reporter, as recorded above)           12:22  
18                   THE WITNESS: Not as much, no.           12:22  
19   BY MR. MORIARTY:           12:22  
20           Q.       So --           12:22  
21           A.       It's --           12:22  
22           Q.       Go ahead. Mike will get mad at me if I           12:22  
23   cut you off.           12:22  
24                   MR. KERENSKY: That's right.           12:22  
25                   THE WITNESS: I'm not an MD. From what           12:22

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1 I've read in this case, this medication is 12:22  
2 frequently given to people who have heart 12:22  
3 problems and therefore are older. In my 12:22  
4 experience working with the generic industry, 12:22  
5 one of the things that they try to do is to 12:22  
6 make a dosage form very distinct and stand out 12:22  
7 as much as possible so elderly people won't 12:22  
8 confuse medication. 12:22

9 So I think it's very probable that an 12:22  
10 elderly person could have taken a double-thick 12:22  
11 tablet and not know about it. There's such 12:22  
12 trust in this country for what you buy from a 12:23  
13 prescription pharmaceutical. You put it in 12:23  
14 your mouth, you don't even think about it. 12:23

15 Heck, my wife is only 52 years old and 12:23  
16 she looks at her medicine case and she can't 12:23  
17 tell what she's taking if she doesn't have her 12:23  
18 glasses on. 12:23

19 So if it got out there -- and we know 12:23  
20 stuff's been out there -- and it was in 12:23  
21 somebody's medicine cabinet in their house, 12:23  
22 and they took it and not seen it, I think 12:23  
23 that's probable if it was there. 12:23

24 BY MR. MORIARTY: 12:23

25 Q. Okay. Probable. In other words more 12:23

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1 likely than not? 12:23

2 A. I think that it's more likely than not 12:23

3 if they had a double-thick tablet that somebody 12:23

4 has taken them. 12:23

5 Q. If they had a double-thick tablet. 12:23

6 A. We know -- 12:23

7 Q. But you don't know whether it's probable 12:23

8 that anybody got one; right? 12:23

9 A. I don't agree with that statement. 12:23

10 Q. Okay, then show me the data. We have 12:23

11 thousands of lawsuits, dozens and dozens of 12:23

12 lawyers, TV advertising, nationwide recall, 12:23

13 everybody's focusing on Digitek. They could pour 12:23

14 them out on table in their lawyers' offices, but 12:24

15 no one has shown you one; okay? 12:24

16 Are you telling me that they ate them all by 12:24

17 coincidence? Is that what you're going to tell a 12:24

18 jury, yes or no? 12:24

19 A. That they ate them all? 12:24

20 Q. Consumed them all. 12:24

21 A. I don't think they necessarily consumed 12:24

22 them all. I think they might have been thrown out 12:24

23 or disposed on top of it all. 12:24

24 Q. Might have been; okay. 12:24

25 Are you going to tell a jury -- are you going 12:24

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1 to tell a jury in this case that it is sheer 12:24  
2 coincidence that my client made enough 12:24  
3 double-thick Digitek to harm consumers but that 12:24  
4 that could not have been detected by Actavis, 12:24  
5 Mylan, UDL, pharmacists, or consumers. Is that 12:25  
6 what you're going to tell the jury? 12:25  
7 A. I think that there's enough evidence 12:25  
8 here based on failures, systemic chronic failures 12:25  
9 of the quality system that product made it to 12:25  
10 market -- and we know that it did in at least a 12:25  
11 couple of circumstances with respect to 12:25  
12 pharmacists' reports. And that out of sheer 12:25  
13 volume of tablets produced that it got to the 12:25  
14 consumer and somebody took it and got hurt. 12:25  
15 Q. All right. So you have one tablet in 12:25  
16 2004 and one -- if you believe that report in 12:25  
17 2008 -- out of somewhere close to a billion 12:25  
18 Digitek tablets; right? That's all that you know 12:25  
19 about; is that right? Yes or no. 12:25  
20 A. Say that again, please. 12:26  
21 Q. You have one report of a tablet in 2004 12:26  
22 that was actually measured. You have a report 12:26  
23 maybe by somebody with the initials CSC after 12:26  
24 their name, looking at a blister pack, seeing a 12:26  
25 tablet in there that might have been 12:26

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1 double-thick. That's two tablets between 2004 and 12:26  
2 2008 out of close to a billion that were made and 12:26  
3 distributed. 12:26

4 Is that all the evidence that you have that 12:26  
5 double-thick Digitek made it to the hands of 12:26  
6 pharmacists or consumers? 12:26

7 A. With the data I've reviewed to this 12:26  
8 point, yes. 12:26

9 Q. Okay. So let me ask my question again. 12:26

10 A. Okay. 12:26

11 Q. Are you going to tell a jury that it is 12:26  
12 a -- that my client made enough 12:26  
13 out-of-specification Digitek to harm consumers but 12:26  
14 not enough to be detected by in-process, finished 12:27  
15 process testing at Actavis, any testing that 12:27  
16 Mylan, UDL did, and also escaped the detection of 12:27  
17 pharmacists and the FDA and the consumers 12:27  
18 themselves? 12:27

19 Is that what you're going to tell the jury, 12:27  
20 yes or no? 12:27

21 A. Yes. But I think there's enough 12:27  
22 information here to throw substantial doubt. I'll 12:27  
23 answer this question, too. I've been in this 12:27  
24 industry since 1992 and consulting for about 12 12:27  
25 years now and at about day two in reviewing these 12:27

1 documents, especially with respect to the EIRs, 12:27  
2 this is the first time I went up to my medicine 12:27  
3 cabinet and I looked for anything that had an 12:28  
4 Actavis label on it and flushed it down the toilet 12:28  
5 because it is that gross in terms of what I was 12:28  
6 seeing. 12:28  
7 MS. DONAHUE: Objection. Move to 12:28  
8 strike. Non-responsive. 12:28  
9 MR. MORIARTY: Are you done? 12:28  
10 THE VIDEOGRAPHER: Five minutes. 12:28  
11 BY MR. MORIARTY: 12:28  
12 Q. Are you done with that answer? 12:28  
13 A. For now, yes. 12:28  
14 MR. MORIARTY: Move to strike. 12:28  
15 BY MR. MORIARTY: 12:28  
16 Q. Here's Exhibit 27. Did you ever see it 12:28  
17 before the other day? 12:28  
18 A. No, and I'm not sure if I saw this one 12:28  
19 for sure. I just -- I said before, the 484 stuff 12:28  
20 I have never saw before. 12:28  
21 Q. Have you ever seen 28 before today -- 12:28  
22 before the other day, excuse me -- Exhibit 28? 12:28  
23 A. No. 12:28  
24 Q. Have you ever seen Exhibit 29 before the 12:28  
25 other day? 12:28

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1 A. Before the other day, no, that I know 12:28

2 of. 12:28

3 Q. Have you ever seen Exhibit 30 before the 12:28

4 other day? 12:29

5 A. No. 12:29

6 Q. Have you ever seen Exhibit 31 before the 12:29

7 other day? 12:29

8 A. As I said before, anything related to 12:29

9 the 484 program I didn't have until yesterday. 12:29

10 Q. So then I assume the answer is the same 12:29

11 to 32, 33, and 34, all of which are additional 12:29

12 484s done by the FDA, testing my client's product 12:29

13 and finding it to be within its specifications. 12:29

14 A. For these particular lots and these 12:29

15 particular samples. 12:29

16 Q. Have you ever seen an FDA report where 12:29

17 they verified that a double-thick tablet made it 12:29

18 to the marketplace in 2005, 6, 7, or 8? 12:29

19 A. In the documents I reviewed, no. 12:30

20 MR. MORIARTY: How many minutes? 12:30

21 THE VIDEOGRAPHER: We have three. 12:30

22 MR. MORIARTY: Let's just take our lunch 12:30

23 break now. 12:30

24 THE VIDEOGRAPHER: The time is 12:30

25 12:31 p.m. We're going off the record 12:30



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1	briefly.	12:30
2	(Lunch break)	01:09
3	THE VIDEOGRAPHER: The time is now	01:09
4	1:12 p.m. We are back on record. This is the	01:10
5	beginning of tape four.	01:10
6	BY MR. MORIARTY:	01:10
7	Q. One of the things that you were going to	01:10
8	do at the lunch break is find the reference to the	01:10
9	1,300 extra thick tablets. Did you find it?	01:10
10	A. Meghan found it and she left. So...	01:10
11	MR. KERENSKY: Let me call her.	01:10
12	MR. MORIARTY: She found it and didn't	01:10
13	give it to you?	01:10
14	MR. KERENSKY: She said she had it in	01:10
15	hand.	01:10
16	MR. MORIARTY: Okay.	01:10
17	MR. KERENSKY: Let's keep going and I	01:10
18	will see if I have --	01:10
19	MR. FITZPATRICK: Here is what Meghan was	01:10
20	talking about. It's in your report. This is	01:10
21	what she's talking about.	01:10
22	THE WITNESS: Right. A-11, yeah.	01:10
23	MR. MORIARTY: Can somebody clue me in?	01:10
24	THE WITNESS: A-11.	01:10
25	MR. FITZPATRICK: No.	01:10

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1 BY MR. MORIARTY: 01:11

2 Q. A-11 is the reference which in your 01:11

3 index says FDA form 483, observation from 01:11

4 inspections spanning October 29 to November 2001; 01:11

5 correct? 01:11

6 A. That's what it says in the report, yes. 01:11

7 Q. And it has to do with -- 01:11

8 A. Here we go. 01:11

9 Q. And it has to do with thin tablets 01:11

10 observed by packaging personnel and they visually 01:11

11 inspected and rejected 1,600 tablets; is that 01:11

12 right? 01:11

13 A. During packaging, 1,600 tablets, yes. 01:11

14 Q. Thin? 01:11

15 A. Thin, short weight. 01:11

16 Q. Well, first of all, I know we covered 01:11

17 this earlier, but these aren't tablets that were 01:11

18 even close to the recall period; correct? 01:12

19 A. The recall was in? 01:12

20 Q. The recall was in April of '08. 01:12

21 A. Okay. 01:12

22 Q. For tablets going back about two years. 01:12

23 A. Yes. 01:12

24 Q. So this isn't even close to the recall 01:12

25 period; right? 01:12

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1 A. No. 01:12

2 Q. And this isn't -- this 483 that you're 01:12

3 referring to -- your A-11 -- reference, isn't 01:12

4 about thin tablets that made it out of the plant 01:12

5 and to consumers; correct? 01:12

6 A. This specifically has to do with their 01:12

7 process and procedure for detecting these types of 01:12

8 tablets. 01:12

9 Q. Which -- 01:12

10 A. The observation. 01:12

11 Q. Which they detected and rejected; 01:12

12 correct? 01:12

13 A. Those specific ones, but as the 01:12

14 observation says here, there's no assurance that 01:12

15 this was taken care of properly and it could have 01:12

16 expanded. 01:13

17 Q. Did you ever see any report from any 01:13

18 document -- FDA or a company -- to indicate that 01:13

19 there were thin tablets in the hands of 01:13

20 pharmacists or consumers in 2001 or 2002? 01:13

21 A. Perhaps. 01:13

22 MR. MORIARTY: Go off the video record, 01:13

23 please. 01:13

24 THE VIDEOGRAPHER: The time is now 01:13

25 1:16 p.m. and we're going off the record 01:13

25 just this one. 01:15

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1 Q. Do you have some documentation that thin 01:15  
2 tablets were in the hands of pharmacists and 01:15  
3 consumers when they did that recall in 1990 that 01:15  
4 you were just talking about? 01:15

5 A. I don't have any documents to support 01:15  
6 that. Just what was given to me. 01:15

7 Q. So you don't have some reference to 01:15  
8 1,300 super- or double-thick tablets anywhere? 01:15

9 A. I misspoke. It was the 1,600. 01:15

10 Q. All right. No, but I'm talking about 13 01:15  
11 or 1,600 extra-thick tablets in '05, '06, '07 or 01:15  
12 '08. 01:16

13 A. No. 01:16

14 Q. Okay. This is Exhibit 35. Have you 01:16  
15 seen this? Did you see this ever -- and if so, 01:16  
16 when? 01:16

17 A. This may be part of the document set 01:16  
18 that was given to me yesterday along with the 484 01:16  
19 stuff. 01:16

20 Q. Well, did you look at it? 01:16

21 A. If it's part of that set -- which I can 01:16  
22 check -- the answer would be yes. I'll check. 01:16

23 Q. Watch out. The screen is on the back of 01:17  
24 your chair. Are you looking for the document 01:17  
25 itself or a list? 01:17

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1 A. No, the document itself. 01:17

2 Q. Bring them all over. 01:17

3 A. All right. 01:17

4 Q. Because I've got plenty to ask you 01:17  
5 about. 01:17

6 A. Okay. 01:17

7 THE VIDEOGRAPHER: Just so we're clear, 01:17  
8 we're still off the video record. 01:17

9 MR. MORIARTY: You mean I asked him that 01:17  
10 whole sequence of questions about the 1,300 01:17  
11 tablets and I wasn't on the video? 01:17

12 THE VIDEOGRAPHER: Yes. 01:18

13 MR. MORIARTY: You got it? 01:18

14 THE COURT REPORTER: Yes, I did. 01:18

15 (Back on the video record) 01:18

16 BY MR. MORIARTY: 01:18

17 Q. Okay. And this is -- UDL or Mylan 01:18  
18 subcontracted with Celsis Analytical Services to 01:18  
19 test three samples from three batches of Digitek; 01:18  
20 correct? 01:18

21 A. Yes, there's Digitek 250, Digitek 250, 01:18  
22 Digitek 125. 01:18

23 Q. And did you read -- 01:18

24 A. Different ones. 01:18

25 Q. Did you read in here that the Digitek 01:18

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1 samples that they tested passed all the tests to 01:19  
2 which they subjected it? Would you like the Bates 01:19  
3 page numbers? The first one, 11687. Do you see 01:19  
4 that? 01:19  
5 A. Assay and dissolution; right? Are you 01:19  
6 speaking to me? 01:19  
7 Q. Yes. 01:19  
8 A. I'm looking at the document. 01:19  
9 Q. I'm giving you the page number to look 01:19  
10 at. 01:19  
11 A. I'm sorry. I didn't understand that. 01:19  
12 Q. 11687. 01:19  
13 A. 11687; okay. 01:19  
14 Q. And it -- this particular batch, they 01:19  
15 ran it assay and a dissolution; correct? 01:19  
16 A. Right. 01:19  
17 Q. And it conformed to both. 01:19  
18 A. Right. I was looking at the results 01:19  
19 over here with respect to the certificate of 01:19  
20 analysis, which has a summary of it all on the 01:20  
21 previous page. 01:20  
22 Q. Next page, 11719. Are you there? 01:20  
23 A. No, I'm not. And this is the one with 01:20  
24 the ugly chromatography. Makes you kind of 01:20  
25 question the results a little bit. 01:20

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1 Q. So you have -- 01:20

2 MS. DONAHUE: Move to strike. 01:20

3 BY MR. MORIARTY: 01:20

4 Q. You have a problem with the 01:20

5 chromatography from both Celsis and FDA? 01:20

6 A. I don't recall. 01:20

7 Q. Because we were talking about FDA 01:20

8 before. 01:20

9 A. Before, yes. This -- just looking at 01:20

10 this, the chromatography is a little bit suspect. 01:20

11 Q. So you have suspect chromatography from 01:20

12 FDA and Celsis? 01:20

13 A. I didn't say that about the FDA. 01:20

14 Q. Yes, you did. That's what we were 01:20

15 talking about was a 484 from FDA. 01:20

16 A. Right. And we didn't specifically talk 01:20

17 about chromatography. 01:20

18 Q. Okay. The record will say what the 01:20

19 record says. 01:20

20 A. Okay. 01:20

21 Q. C11719. This batch tested for again 01:20

22 assay and dissolution. It conformed to both. 01:21

23 A. I'm actually looking at the certificates 01:21

24 of analysis, which are a better summary, which is 01:21

25 in the pages before. 01:21



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1 Q. But the certificate of analysis comes 01:21  
2 from Actavis, does it not? 01:21

3 A. No, I'm pretty sure that this is a 01:21  
4 summary of the certificate of analysis from -- 01:21  
5 perhaps not. Let's see. 01:21

6 Q. What page are you looking at? 01:21

7 A. The previous page. 11718. 01:21

8 Q. Doesn't it says Actavis Totowa, LLC, 01:21  
9 right at the top? 01:21

10 A. Yeah. That doesn't necessarily mean 01:21  
11 that that's Actavis's data. Let's see. Is it 01:21  
12 their C of A.? You can't just assume it. 01:21  
13 Sometimes labs put the client's name at the top of 01:21  
14 the documents, so... 01:21

15 Q. Look at 11719, which is Celsis' report 01:21  
16 of analysis. 01:22

17 A. Okay. 01:22

18 Q. Did the Digitek conform to the two tests 01:22  
19 to which they subjected it? 01:22

20 A. Let's see. Conforms, yes, for assay and 01:22  
21 dissolution. 01:22

22 Q. Let's go to page 11748, the report of 01:22  
23 analysis from the third batch that they tested. 01:22  
24 Did it pass assay and dissolution? 01:22

25 A. Yes, for the samples they tested. 01:22

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1 Q. Was Exhibit 69 among the materials that 01:22  
2 the Plaintiffs' lawyers supplied you the other 01:23  
3 day. Does it look familiar? 01:23

4 A. I -- to tell you truth, I can't -- I'm 01:23  
5 looking at so many different documents. To make a 01:23  
6 statement that I've looked at this, it's just not 01:23  
7 possible. And many of these documents I looked at 01:23  
8 six months ago, didn't even come close to 01:23  
9 reviewing it until two days ago. So you'll have 01:23  
10 to bear with me. I apologize. Yes. 01:23

11 Q. So you had it to review? 01:24

12 A. I did. 01:24

13 Q. And they received this Digitek in April 01:24  
14 of 2008 right before the recall; correct? First 01:24  
15 page, right at the top. Date received. 01:24

16 Do you see that? 01:24

17 A. I do. I'm looking at the receiving 01:24  
18 inspection form instead, which I trust more than 01:24  
19 the electronic printout. Okay. They inspected it 01:24  
20 in April 2008, yes. 01:24

21 Q. And if you go back to page 7655? 01:24

22 A. Uh-huh. 01:24

23 Q. They measured 20 Digitek tablets, didn't 01:24  
24 they? 01:25

25 A. Uh-huh. 01:25

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1 Q. And they were all within the specs, 01:25  
2 weren't they? 01:25

3 A. For the 20 they measured, yes. 01:25

4 Q. Does it appear to you that they 01:25  
5 subjected it to any additional analysis? 01:25

6 A. Based on what document? 01:25

7 Q. Well, the one in front of you, Exhibit 01:25  
8 69. 01:25

9 A. Okay. 01:25

10 Q. It doesn't appear to you that they did 01:26  
11 assay or dissolution; correct? 01:26

12 A. I'm looking. 01:26

13 Q. Just from skimming through, do you see 01:27  
14 any assay? 01:27

15 A. Yeah, I do. That's why I'm taking my 01:27  
16 time. Because it look like they're making an 01:27  
17 assay. 01:27

18 Q. Are you looking at the certificate of 01:27  
19 analysis or -- 01:27

20 A. No, I'm not. I'm looking at this letter 01:27  
21 here and I'm trying to determine. It's very 01:27  
22 difficult to look at somebody else's testing and 01:27  
23 control documents because they're not all the 01:27  
24 same. 01:27

25 Q. And what page are you looking at? 01:27

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1           A.       I'm looking at 7656, the Mylan quality           01:27  
2    assurance assay result. We acknowledge the assay           01:27  
3    result is outside UDL's parameter, which is           01:27  
4    interesting. So UDL tested it and it was out --           01:27  
5    for assay and it was outside their parameters.           01:27  
6           Q.       Was it outside the ANDA FDA-approved           01:27  
7    United States pharmacopeia specifications?           01:27  
8           A.       I don't know.           01:27  
9           Q.       Do you know what the USP specs are?           01:27  
10          A.       I don't have the USP in front of me,           01:27  
11   yes.           01:27  
12          Q.       If you assume that it was 90 to 105           01:27  
13   percent, then this would be within the specs;           01:27  
14   correct?           01:28  
15          A.       I'm not going to assume anything.           01:28  
16                  MR. KERENSKY: He's allowed to ask you           01:28  
17   that type of question.           01:28  
18                  THE WITNESS: Yeah, but...           01:28  
19                  MR. KERENSKY: If that's the true spec.           01:28  
20   Is that what they found?           01:28  
21                  THE WITNESS: What did you say was the           01:28  
22   true spec to be?           01:28  
23   BY MR. MORIARTY:           01:28  
24          Q.       90 to 105 percent?           01:28  
25          A.       90 to 105? If that assay limit is 97.4,           01:28

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1 then it does fall within that -- if that's the 01:28

2 case. But it doesn't fit UDL's one. 01:28

3 Q. Do you know whether people have 01:28

4 testified in this case that UDL's specs are 01:28

5 tighter than the ANDA FDA-approved USP specs? 01:28

6 Simple question. Do you know anybody who 01:28

7 testified to that? 01:28

8 A. I know it's a simple question. I'm just 01:28

9 trying to remember the documents that I reviewed, 01:28

10 as to whether in fact there is a statement to the 01:28

11 effect that there is a tighter spec. As far as 01:28

12 testifying goes, not that I know of. 01:28

13 MR. KERENSKY: Very good. That's all 01:29

14 he's asking you. 01:29

15 THE WITNESS: Okay, okay. 01:29

16 MR. MORIARTY: Exhibit 70. This is a UDL 01:29

17 analysis documents for another batch of 01:29

18 Digitek they received in February of 2008. 01:29

19 THE WITNESS: Okay. Assuming the date 01:29

20 format 3/5/08 is February, yes. Or March 01:29

21 rather. 01:29

22 BY MR. MORIARTY: 01:29

23 Q. So at page 7671, did they measure 20 01:29

24 more Digitek tablets? 01:29

25 A. It appears they did, yes. 01:29

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1 Q. And were they all within the specs as 01:29  
2 far as you know? 01:29

3 A. It's a good point. I don't know if I 01:30  
4 have the written specs here to do that, but 01:30  
5 assuming that the range is appropriate as stated 01:30  
6 on here, then, yes. I don't have the spec sheet. 01:30  
7 I don't think it's here, is it? C of A. Let's 01:30  
8 see. No. It's a good point. What spec are they 01:30  
9 using? 01:30

10 Q. Well, the ANDA -- the FDA would have 01:30  
11 approved a thickness range in the ANDA; correct? 01:30

12 A. Correct. And but the key being here is, 01:30  
13 is that we don't know what UDL specs they're 01:30  
14 referring to, what the spec is. 01:30

15 Q. My question is whether it's passing the 01:30  
16 FDA-approved USP specs. 01:30

17 A. I don't know. 01:31

18 Q. Okay. 01:31

19 A. It's not here. 01:31

20 Q. So now I've asked you about a number of 01:31  
21 FDA 484s and I've started to ask you about these 01:31  
22 UDL and Celsis lab documents. Do you know how 01:31  
23 many of the batches that have been tested in the 01:31  
24 documents that I've asked you about so far are 01:31  
25 among the recalled batches? 01:31

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1 A. No, I don't know that number. 01:31

2 Q. This is Exhibit 71. Was it among the 01:31

3 materials that you reviewed in the last few days? 01:31

4 A. Yes. 01:31

5 Q. At page -- this is a Digitek batch 01:31

6 received at UDL in January in January of 2008; 01:31

7 correct? 01:32

8 A. Yes. 01:32

9 Q. And at page 7688 did they measure 20 01:32

10 more? 01:32

11 A. Yes. 01:32

12 Q. Is there any indication in this document 01:32

13 at all that any of them were outside the 01:32

14 FDA-approved specifications? 01:32

15 A. Again, I'm not trying to be difficult. 01:32

16 I don't know what the FDA specifications are. I 01:32

17 have to assume that that's what they're measuring 01:32

18 them against. There's no spec sheet, there's no 01:32

19 method, there's no nothing. 01:32

20 Q. All right. 01:32

21 A. Chances are if what you're saying is 01:32

22 correct that that UDL has -- you implied that UDL 01:32

23 has a tougher standard, this may be tougher or may 01:33

24 be wider. I don't know. 01:33

25 Q. Okay. 01:33

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1 A. I see the assay was low again, too. 01:33

2 Q. Is that assay outside the US FDA -- the 01:33

3 United States Food and Drug Administration's 01:33

4 approved specs for this product? 01:33

5 A. If we go with your statement, what was 01:33

6 it 98 to? 01:33

7 Q. 90 to 105 percent. 01:33

8 A. 90 to 105, yes, then it would fall in 01:33

9 that spec. 01:33

10 Q. This is Exhibit 72. Is this a Digitek 01:33

11 batch received by UDL in June of 2007? You can 01:33

12 just look at the one I gave you. You don't need 01:34

13 to pull out your own. 01:34

14 A. All right. 01:34

15 Q. Is that what this is? 01:34

16 A. June. 01:34

17 Q. 2007? 01:34

18 A. Yes. 01:34

19 Q. Okay. And at page 5815 I believe it is, 01:34

20 did they measure 20 more? 01:34

21 A. They did. 01:34

22 Q. Any indication that any of them are 01:34

23 outside the FDA-approved specs? 01:34

24 A. Unlike the assay -- perhaps, you know. 01:34

25 Do you know what the thickness that the filed spec 01:34



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1 is? Because they do point out that it failed 01:35

2 UDL's thickness, and we don't know whether it's 01:35

3 tighter or wider than -- 01:35

4 Q. We do know because there's been 01:35

5 testimony. Their specs are tighter than the FDA's 01:35

6 approved specs. 01:35

7 A. Okay. Because those -- 01:35

8 Q. Those all passed. 01:35

9 A. They did fail -- four tabs failed 01:35

10 thickness here, but the spec that UDL has, they're 01:35

11 measuring this right here, that -- that is -- the 01:35

12 question here is that is the filed spec, do we 01:35

13 know that? 01:35

14 Q. What page? 01:35

15 A. The one you had me look at, 5815 is it? 01:35

16 Q. There is no spec on that page. 01:35

17 A. No. 01:35

18 Q. So my question is just is there any 01:35

19 indication in the document that any of the tablets 01:35

20 were outside the FDA's approved specs for the 01:35

21 product? 01:36

22 A. We can't say that one way or the other 01:36

23 because we don't have the USP spec for thickness 01:36

24 or the file spec. 01:36

25 Q. You don't know the answer to the 01:36

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1 question. 01:36

2 A. I'd know the answer to the question if I 01:36

3 had the spec from the ANDA. It's not here. 01:36

4 Q. I'm showing you what has been marked as 01:36

5 Exhibit 73; okay. 01:36

6 A. Would you like me to check these and see 01:36

7 if I had this before? 01:36

8 Q. No, sir. Look at the second page and -- 01:36

9 A. 478969? 01:37

10 Q. Yes. Okay. Do you see the specs for 01:37

11 Actavis and UDL at the top? 01:37

12 A. I'm looking. 01:37

13 Q. Do you see that? 01:37

14 A. I see that. 01:37

15 Q. Aren't the UDL specs tighter than the 01:37

16 Actavis specs? 01:37

17 A. The reason I'm hesitating is I'm seeing 01:37

18 how it's written, and I'm trying to make sure that 01:37

19 I got it in the right order. So please bear with 01:38

20 me. Actavis has -- on the 250 microgram tablet, 01:38

21 Actavis has narrower limit than UDL has. On the 01:38

22 upper end, they do as well. So they're different 01:38

23 and -- tighter is not -- 01:38

24 Q. Okay. Let's go back to basic math 01:38

25 here. 01:38

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1	A.	Yeah.	01:38
2	Q.	If the FDA-approved range for .250	01:38
3		microgram Digitek is 2.7 millimeters to 3.7.	01:39
4	A.	Right.	01:39
5	Q.	3.15 to 3.29 -- the UDL spec -- is	01:39
6		tighter?	01:39
7	A.	Broader; right.	01:39
8	Q.	No, actually it's tighter.	01:39
9	A.	The UDL?	01:39
10	Q.	It's narrower. Isn't 3.15 larger than	01:39
11		2.7?	01:39
12	A.	Yeah.	01:39
13	Q.	And isn't 3.29 less than 3.7?	01:39
14	A.	The way this is written --	01:39
15	Q.	Yes or no. Is --	01:39
16	A.	No, no, no, no.	01:39
17	Q.	Is 3.29 less than 3.7?	01:39
18	A.	On that one, yes.	01:39
19	Q.	Okay.	01:39
20	A.	But on the other end, it's not.	01:39
21	Q.	3.15 is --	01:39
22	A.	Is broader. You've got a broader range	01:39
23		between those two specs than you do for Actavis.	01:39
24	Q.	Okay. Tell you what. Let's look at the	01:39
25		sentence:	01:39

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1 "It should be noted that UDL's tolerances for 01:39  
2 creation of blister cavity size are tighter than 01:40  
3 the manufacturer's tolerances for thickness and 01:40  
4 UDL's maximum tolerance is used during the 01:40  
5 creation of blister tubing." 01:40

6 Are you writing on that too?" 01:40

7 A. No, I'm not. 01:40

8 Q. Did I read that correctly? 01:40

9 A. Yes. 01:40

10 Q. Are you telling me that UDL is wrong? 01:40

11 A. Okay. The thickness variance between 01:40

12 3.7 and 2.7 is 1.0; okay? If you go 3.29 to 01:40

13 3.15. All right. Okay. .14. You're right. I 01:40

14 just want to make sure. 01:40

15 Q. Okay. So, the Actavis specs are -- 01:40

16 FDA-approved that Actavis specs are wider than 01:40

17 UDL's for both doses. 01:40

18 A. Yes. 01:40

19 Q. Okay. 01:40

20 A. Just the range is different. 01:41

21 Q. Okay. I'm handing you what has been 01:41

22 marked as Exhibit 83. This is a correspondence 01:41

23 between UDL and Celsis, is it not, about Digitek 01:41

24 tablets? 01:41

25 A. This is a report -- what was the 01:42

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1 question again? 01:42

2 Q. Is this a communication between UDL and 01:42

3 Celsis about three batches of Digitek that they 01:42

4 were testing for stability. It's more than three 01:42

5 batches. Is this what this is about is stability 01:42

6 testing and Digitek? 01:42

7 A. It appears to be about stability 01:42

8 testing, and I think there is more -- you're 01:42

9 correct on that. 01:42

10 Q. When you run stability testing, do you 01:42

11 also run assay? 01:42

12 A. Yes. 01:42

13 Q. Did the Digitek that they tested in 01:42

14 Exhibit 83 pass all the specs? Why don't you go 01:43

15 off the video record while we -- 01:44

16 THE VIDEOGRAPHER: The time is now 01:44

17 1:47 p.m. We are going off the video record 01:44

18 briefly. 01:44

19 (Short break.) 01:47

20 THE VIDEOGRAPHER: The time is now 01:48

21 1:51 p.m. We are back on record. 01:49

22 BY MR. MORIARTY: 01:49

23 Q. Did it pass all the tests to which 01:49

24 Celsis and UDL subjected it for stability and 01:49

25 assay? 01:49



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1 well, which are problematic with respect to the 01:50

2 manufacturing of Digitek in my opinion. 01:50

3 Q. Show me a document anywhere that -- 01:51

4 where the FDA questions the process validation of 01:51

5 Digitek. 01:51

6 A. Within a specific time frame or -- 01:51

7 Q. 2005, 6, 7 or 8. I mean do you have any 01:51

8 evidence that people in this litigation took 01:51

9 tablets from the 90s or the early 2000s? 01:51

10 A. I have no idea. I doubt it. 01:51

11 Q. Do you know what the expiration is on 01:51

12 this product? 01:51

13 A. I do not. 01:51

14 Q. So? 01:51

15 A. It's reasonable to be assumed that no. 01:51

16 Q. What I want to know is if you have some 01:51

17 data from FDA from 2006, 7, or 8 to indicate that 01:51

18 Actavis's process validation on the manufacture 01:51

19 and testing of Digitek was a problem. 01:52

20 Go off the record again. 01:52

21 THE VIDEOGRAPHER: The time is 1:55 p.m. 01:52

22 We're going off the record briefly. 01:52

23 (Short break) 01:55

24 THE VIDEOGRAPHER: The time is now 01:55

25 1:58 p.m. We are back on the record. 01:56

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1 THE WITNESS: If you look at the warning 01:56  
2 letter that was issued in February 2007, one 01:56  
3 of the findings by the FDA is no procedures 01:56  
4 for conducting bulk hold time studies. In my 01:56  
5 opinion and experience that, again, back to 01:56  
6 this warning letter, it says procedures for 01:56  
7 conducting bulk holding time studies. That 01:56  
8 falls into the purview of process validation. 01:56  
9 So the answer would be yes, based on that 01:56  
10 warning letter. 01:56  
11 MR. ANDERTON: What page of the report 01:56  
12 are you referring to? 01:56  
13 THE WITNESS: I'm going through my 01:56  
14 document. 01:56  
15 MR. ANDERTON: I understand. What page? 01:56  
16 THE WITNESS: I would need to pull out 01:56  
17 the -- 01:56  
18 MR. KERENSKY: What page of the report? 01:56  
19 MR. ANDERTON: What page of the report 01:56  
20 are you looking at? 01:56  
21 THE WITNESS: I'm sorry. 41. 41, 42. 01:56  
22 Goes over to 42. 01:56  
23 BY MR. MORIARTY: 01:57  
24 Q. From a February 2007 warning letter; 01:57  
25 right? 01:57



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1 A. Correct. 01:57

2 Q. Actually doesn't say anything about 01:57

3 process validation, does it? 01:57

4 A. Bulk holding time would be part of the 01:57

5 process validation in my experience. 01:57

6 Q. That's nice. I'm asking whether the 01:57

7 warning letter says something about the process 01:57

8 validation or whether it just refers to bulk 01:57

9 holding times. 01:57

10 A. I'll have to go back to the EIR to look 01:57

11 specifically at that section. 01:57

12 Q. Well, what is -- first of all, did it 01:57

13 relate to Digitek? 01:57

14 A. Unless I go back and look at the report, 01:57

15 I can't answer that question. 01:57

16 Q. So you can't identify for me right now 01:57

17 -- 01:57

18 A. In this document. 01:57

19 Q. -- whether there's anything specific to 01:57

20 Digitek? 01:57

21 A. No, I'm going back to the FDA document. 01:57

22 Q. Do you know whether that observation is 01:58

23 remediated and whether the FDA was satisfied with 01:58

24 the company's actions in that regard for whatever 01:58

25 product that was? 01:58

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1 A. Specifically, no. However, considering 01:58  
2 they went to consent decree, I doubt if they did. 01:58

3 Q. Okay. Let me just make clear while 01:58  
4 we -- see if we can find that. As you sit here 01:59  
5 right now, you don't know if that was a finding 01:59  
6 specific to Digitek; correct? 01:59

7 A. Correct. 01:59

8 Q. And you don't know as you sit here now 01:59  
9 whether it was remediated to the satisfaction of 01:59  
10 FDA; correct? 01:59

11 A. That's a fair statement. 01:59

12 Q. Right. 01:59

13 A. The fact that it relates to Digitek or 01:59  
14 not is an interesting question in itself because 01:59  
15 if you are not doing those kind of things, it is a 01:59  
16 failure of your quality system in general and 01:59  
17 manufacturing controls. 01:59

18 Q. But as you, as a consultant, would you 01:59  
19 want to know what specific drug products that 01:59  
20 impacts? 01:59

21 A. Sure. But in a bigger picture you'd 01:59  
22 want to make sure that it's not impacting -- you 02:00  
23 don't have the system in place that's going to 02:00  
24 impact everything. 02:00

25 Q. Okay. I'm handing you Exhibit 63. Have 02:00

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1 you ever seen this section of the regulatory 02:00

2 procedure manual? First of all, did you ever read 02:00

3 the regulatory proceduring manual from the FDA? 02:00

4 A. If you can find it. Because the links 02:00

5 change frequently and it's often difficult to find 02:00

6 these kinds of things. 02:00

7 Q. But you do consult with it from time to 02:00

8 time? 02:01

9 A. Rarely. 02:01

10 Q. Okay. 02:01

11 A. Maybe once or twice. 02:01

12 Q. Let's go to page -- the second page. 02:01

13 A. Uh-huh. 02:01

14 Q. Page 4-2? 02:01

15 A. Uh-huh. 02:01

16 Q. Fourth full paragraph. 02:01

17 A. Okay. 02:01

18 Q. The first sentence says: 02:01

19 "A warning letter is informal and advisory." 02:01

20 Do you agree with the FDA on that statement about 02:01

21 their own documents? 02:01

22 A. Informal and advisory. I've obviously 02:01

23 never read this section before. It's what it 02:01

24 says. 02:01

25 Q. Okay. Well, it's the FDA commenting on 02:01

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1 the force and effect of its own documents. Do you 02:01  
2 have some reason to disagree with the FDA in that 02:01  
3 regard? 02:01

4 A. In my experience, the answer to that, 02:01  
5 yes. Because in my experience a warning letter is 02:01  
6 taken with great seriousness and remediation 02:01  
7 actions spin-off of it. I'm in a major consulting 02:02  
8 project right now, responding to a warning 02:02  
9 letter -- as numerous companies are in the 02:02  
10 industry. You don't just take it as informal. 02:02  
11 You address it. It's standard industry practice. 02:02

12 Q. Well, you're looking at it from the 02:02  
13 perspective of the company when you just answered 02:02  
14 that question are you not? 02:02

15 A. I would I'm looking at it from the 02:02  
16 perspective of the agency, too. The agency 02:02  
17 expects you to respond to a warning letter pretty 02:02  
18 seriously as well. That's why it goes to the CEO. 02:02

19 Q. The FDA has a regulatory procedures 02:02  
20 manual, and in it, it says that a warning letter 02:02  
21 is informal and advisory. And you disagree with 02:02  
22 the FDA on an announcement that they make in their 02:02  
23 own publication; am I correct? 02:02

24 A. I'm not disputing what it says here, but 02:02  
25 the reality on the ground is that warning letters 02:02

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1 by the agency and -- all companies is taken with 02:02

2 great seriousness, and they surely are not 02:03

3 addressed in an informal and advisory fashion. 02:03

4 Q. Okay. 02:03

5 A. That's my professional opinion. 02:03

6 Q. Third sentence of that paragraph: 02:03

7 "FDA does not consider warning letters to be 02:03

8 final agency action on which it can be sued." 02:03

9 Do you agree with that or disagree with that? 02:03

10 A. "FDA does not consider warning letters 02:03

11 to be final agency action on which it can be 02:03

12 sued." 02:03

13 I was under the impression that you can't sue 02:03

14 the FDA. Maybe I'm wrong. 02:03

15 Q. Do you disagree with the statement or 02:03

16 not? 02:03

17 A. It's not final agency action by any 02:03

18 stretch of the imagination. 02:03

19 Q. Okay. Thank you. 02:03

20 Next page, 4-3, under the first paragraph. At 02:03

21 the margin it says "in certain situations." Do 02:04

22 you see that? Item number 4 under that uses the 02:04

23 word super-potency. Is that a -- is that term in 02:04

24 the industry that you understand? 02:04

25 A. Sub-potent or super potent? 02:04

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1 Q. It says super-potency; right there? 02:04

2 A. Yes. 02:04

3 Q. That's a term you understand. 02:04

4 A. Sub-potent, super-potent, yes. 02:04

5 Q. I'm showing you Exhibit 64. This is a 02:04

6 different chapter in the regulatory procedures 02:04

7 manual. I would like you to go to page 10-6. 02:04

8 A. Okay. 02:05

9 Q. Section 10-2-3. It says: 02:05

10 "When it is consistent with the public 02:05

11 protection responsibilities of the agency and if a 02:05

12 violative situation does not present a danger to 02:05

13 health or does not constitute intentional, gross, 02:05

14 or flagrant violations, it is FDA's policy to 02:05

15 afford individuals and firms an opportunity to 02:05

16 voluntarily take appropriate and prompt corrective 02:05

17 action prior to the initiation of an enforcement 02:05

18 action." 02:05

19 Is that consistent with your experience? 02:05

20 A. Yes. In that voluntary can mean a 02:06

21 consent decree, as you pointed out earlier. 02:06

22 Q. Okay. Let's go to the next page, 10-7. 02:06

23 Under 10-2-4, procedures: 02:06

24 "Warning letters are the principal means by 02:06

25 which the agency provides prior notice of 02:06

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1 violations and of achieving voluntary 02:06  
2 compliance." 02:06  
3 Did I read that correctly? 02:06  
4 A. That's what it says. 02:06  
5 Q. Is that consistent with your experience? 02:06  
6 A. No. It's always been my understanding 02:06  
7 that the 483 was the first documentation of lack 02:06  
8 of compliance. 02:06  
9 Q. Okay. Well, later -- but a warning 02:06  
10 letter is a means of getting voluntary compliance, 02:06  
11 whether it comes first or second. That's the 02:06  
12 point of it; right? 02:07  
13 A. It is a step up in the ladder with 02:07  
14 respect to seriousness of lack of compliance. 02:07  
15 That's what it is. 02:07  
16 Q. At the end of paragraph I was reading 02:07  
17 from it says: 02:07  
18 "Other less formal ways include the 02:07  
19 following." And item two is the 483; correct? Is 02:07  
20 that what it says? 02:07  
21 A. I -- 02:07  
22 Q. Is that what's there? 02:07  
23 A. This is -- this is what it says. But I 02:07  
24 can tell you 483s are not informal by any stretch 02:07  
25 of the imagination. 02:07

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1	Q.	Well, FDA says they are; correct?	02:07
2	A.	In their documents manual that's what	02:07
3		they do.	02:07
4	Q.	Okay.	02:07
5	A.	But in reality in the world, 483s are	02:07
6		not informal.	02:07
7	Q.	All right. So if a warning letter is	02:07
8		not a final agency action, and a 483 is considered	02:07
9		by FDA less formal than a warning letter, you	02:07
10		would agree that FDA doesn't consider 483s to be	02:08
11		final agency action; is that true?	02:08
12	A.	Say that again, please.	02:08
13	Q.	In your opinion is a 483 a final agency	02:08
14		action?	02:08
15	A.	A final agency action? No.	02:08
16	Q.	It even says that right on the 483s	02:08
17		itself, that it's not a final agency action;	02:08
18		correct?	02:08
19	A.	I'd have to go back and look if I may.	02:08
20	Q.	You don't want to trust me on that?	02:08
21	A.	No.	02:08
22	Q.	Find a 483.	02:08
23	A.	Okay.	02:08
24	Q.	You must have several in your stack.	02:08
25		THE VIDEOGRAPHER: Would you like me to	02:08



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1	go off the record?	02:08
2	THE WITNESS: I got one right here.	02:08
3	BY MR. MORIARTY:	02:08
4	Q. You've given me out of your stack	02:08
5	Exhibit -- Plaintiffs' Exhibit 26, which is a 483	02:08
6	from March through May of 2008; correct?	02:08
7	A. Yes.	02:08
8	Q. And in the very top it says they are	02:08
9	inspectional observations and do not represent a	02:09
10	final agency determination regarding your	02:09
11	compliance. Does it say that right in the top box	02:09
12	of the document?	02:09
13	A. Yes. Put it on your stack.	02:09
14	MR. MORIARTY: Okay. How much time on	02:09
15	the tape?	02:09
16	THE VIDEOGRAPHER: 13 minutes.	02:09
17	MR. MORIARTY: Okay.	02:09
18	BY MR. MORIARTY:	02:09
19	Q. Let's talk about just background stuff	02:09
20	for a bit. Have you ever been sued?	02:09
21	A. Yes.	02:09
22	Q. What was the suit about?	02:09
23	A. Landlord-tenant.	02:09
24	Q. Any other suits?	02:09
25	A. Yes.	02:10

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1	Q.	What?	02:10
2	A.	Probate.	02:10
3	Q.	You were sued? A probate case?	02:10
4	A.	Yes.	02:10
5	Q.	Okay. Anything else?	02:10
6	A.	No.	02:10
7	Q.	What was the probate -- when in -- the	02:10
8		landlord-tenant case, were you the landlord?	02:10
9	A.	I was.	02:10
10	Q.	And in the probate case, just give me	02:10
11		the briefest description of what that was about.	02:10
12	A.	I was made administrator of my father's	02:10
13		estate who died without a will.	02:10
14	Q.	Got it. Okay.	02:10
15		So you have not been a Defendant in any other	02:10
16		cases. Have you ever been a Plaintiff in any	02:10
17		lawsuits?	02:10
18	A.	No.	02:10
19	Q.	Your report has appendices that list the	02:10
20		things that you reviewed; correct?	02:10
21	A.	Correct.	02:10
22	Q.	Then in addition to that, you brought	02:10
23		with you today Exhibits 107 and 108 which are	02:10
24		lists of things you reviewed online but did not	02:11
25		printout; correct?	02:11

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1 A. Correct. 02:11

2 Q. Other than what is listed in your report 02:11

3 and 107 and 108, and the 484s and the Celsis 02:11

4 documents that we reviewed today and you told me 02:11

5 you just got, is there anything else you reviewed? 02:11

6 A. There may be some additional documents 02:11

7 in these folders over here. 02:11

8 Q. Are they in one discrete place so you 02:11

9 know what those additional documents are? 02:11

10 A. No. 02:11

11 Q. Did you review any deposition testimony 02:11

12 of any Actavis company witnesses? 02:11

13 A. Yes. 02:11

14 Q. Do you know which ones? 02:11

15 A. Hum. 02:11

16 Q. Are they listed somewhere? 02:11

17 A. They are listed. 02:12

18 Q. Are they listed in the report or in the 02:12

19 107, 108? 02:12

20 A. Probably both. 02:12

21 Q. Okay. Have you read the deposition 02:12

22 testimony of Dr. Semigran who is a cardiologist in 02:12

23 Boston I questioned him. 02:12

24 A. I don't recall. 02:12

25 Q. Did you read the deposition of a Ph.D. 02:12

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1 by the name of Nelson. He's in Cincinnati. I 02:12

2 questioned him. 02:12

3 A. I don't recall. I don't think so. 02:12

4 Q. All right. 02:12

5 A. Those two names don't ring a bell. I 02:12

6 can check. 02:12

7 Q. Have you consulted with any other 02:12

8 pharmaceutical experts in your work on this 02:12

9 case -- subcontractors, in other words? 02:12

10 A. Expert witness? 02:13

11 Q. Yeah. 02:13

12 A. No. 02:13

13 Q. This is Exhibit 93. This is the resume 02:13

14 of yours that we were supplied by the Plaintiffs' 02:13

15 lawyers. Is it current and up-to-date? 02:13

16 A. I have a current copy that I can compare 02:13

17 it against. Would you like me to do that? 02:13

18 Q. As quickly as you can. 02:13

19 A. Okay. Excuse me. I'll just scan 02:13

20 through it, save time. 02:14

21 THE VIDEOGRAPHER: While we are doing 02:14

22 that, we can change the tape. 02:14

23 The time is 2:17 p.m. We're going off 02:14

24 the record. 02:14

25 (Short break) 02:18

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1 THE VIDEOGRAPHER: The time is now 02:18  
2 2:22 p.m. We are back on the record. This is 02:18  
3 the beginning of tape five. 02:19  
4 BY MR. MORIARTY: 02:19  
5 Q. Okay. So the question was does it look 02:19  
6 like your CV is up-to-date? 02:19  
7 A. There are few things here that are 02:19  
8 different. 02:19  
9 Q. Such as? 02:19  
10 A. Such as if I recall right here, there's 02:19  
11 a couple of committees that I -- there's a 02:19  
12 committee that I don't sit on anymore. 02:19  
13 Q. Okay. 02:19  
14 A. And -- 02:19  
15 Q. Is there anything significant that you 02:19  
16 do or have done or have published that is not on 02:19  
17 there? 02:19  
18 A. Yeah, I've actually been hired as an 02:19  
19 adjunct Professor at St. Leo to do online 02:19  
20 education. 02:19  
21 Q. Not a classroom? 02:19  
22 A. No. Distance learning. 02:19  
23 Q. What's the topic? 02:20  
24 A. It's general science. 02:20  
25 Q. Okay. Does Delphi have offices in North 02:20

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1	Carolina?	02:20
2	A. No.	02:20
3	Q. Do you just spend the summers up there?	02:20
4	Was that why we were planning on doing this in	02:20
5	North Carolina in June?	02:20
6	A. Yeah, I'm engaged in a large consulting	02:20
7	project right now.	02:20
8	Q. Got it. How many employees does Delphi	02:20
9	have?	02:20
10	A. Two.	02:20
11	Q. Who are they?	02:20
12	A. Myself and my wife. Permanent.	02:20
13	Q. What's your wife's undergraduate degree	02:20
14	in? I promise I won't show her the tape.	02:20
15	A. Something like modern foreign languages.	02:20
16	Q. Okay. Does she have a graduate degree	02:20
17	in anything?	02:21
18	A. No.	02:21
19	Q. Have you ever consulted with Actavis,	02:21
20	Mylan, UDL, or Amide?	02:21
21	A. Consulted?	02:21
22	Q. Yes, consulted.	02:21
23	A. No.	02:21
24	Q. The Delphi web page indicates that your	02:21
25	business is woman-owned. I assume that's your	02:21

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1	wife?	02:21
2	A. It is.	02:21
3	Q. And what is her job with the company?	02:21
4	A. On a functional basis -- I would have to	02:21
5	go back and look at the sub-S form filing in order	02:21
6	to see what her real title is in that paperwork,	02:21
7	but the functional, she is the bookkeeper.	02:21
8	Q. And did she have independent resources,	02:21
9	if you will, that she contributed to start and run	02:21
10	the business?	02:21
11	A. Could you explain that a little more?	02:22
12	Q. Sure. I mean she owns at least 51	02:22
13	percent of the business; correct?	02:22
14	A. That's correct.	02:22
15	Q. And what was the contribution that led	02:22
16	her to that ownership? Was it cash, was it a car,	02:22
17	was it office equipment, what was it?	02:22
18	A. She and I formed the corporation	02:22
19	together and we made it 51 percent her in order to	02:22
20	take advantage of small business loans if they	02:22
21	became available.	02:22
22	Q. All right. Now you list your clients or	02:22
23	some of them at page 5 to 6 of this exhibit.	02:22
24	A. Uh-huh.	02:22
25	Q. Did any of those consultations have to	02:22

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1 do with extra-thick tablets? 02:22

2 A. Because of confidentiality agreements, I 02:22

3 am not at liberty the discuss anything about 02:22

4 clients. 02:22

5 Q. I didn't ask which client and which 02:22

6 product. So I need to know whether any of those 02:22

7 had to do with extra-thick tablets. 02:22

8 A. No. 02:22

9 Q. Did any of them have to do with 02:22

10 normal-sized tablets with too much active 02:22

11 pharmaceutical ingredient? 02:23

12 A. From a consultant standpoint? 02:23

13 Q. Yes, sir. 02:23

14 A. Perhaps. 02:23

15 Q. In March of 2009, Watson had a recall 02:23

16 for a drug called Propafenone HCL that had too 02:23

17 much active pharmaceutical ingredient in it. Did 02:24

18 you consult with them on that project? 02:24

19 A. No. 02:24

20 Q. Now, what did Laboratory Management 02:24

21 Systems, Inc. do? What did they make? 02:24

22 A. They were a services company that 02:24

23 provided maintenance calibration -- IQ, OQ, PQ 02:24

24 services to the pharmaceutical industry in 02:24

25 addition to compliance concerns. 02:24



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1 Q. So you did not -- whatever role you had 02:24

2 there did not involve the manufacture of any 02:24

3 pharmaceutical dose form; correct? 02:24

4 A. I consulted in the field. 02:24

5 Q. I'm asking whether LMSI didn't 02:25

6 manufacture pharmaceutical -- 02:25

7 A. No, they did not manufacture, no. 02:25

8 Q. What did Restek Corporation do when you 02:25

9 worked for them? 02:25

10 A. Restek's core business is GC and HPLC 02:25

11 column technology. I designed, built, staffed, 02:25

12 qualified after writing a business plan, the 02:25

13 contract analytical laboratory for them. 02:25

14 Q. They did not manufacture any dose form 02:25

15 of pharmaceutical products; is that correct? 02:25

16 A. That's correct. 02:25

17 Q. What did Somerset Pharmaceuticals do 02:25

18 when you worked with them in '95 and '97? 02:25

19 A. We were a small pharmaceutical company 02:25

20 that was doing research and development and 02:26

21 supporting, when necessary, manufacturing of 02:26

22 certain products. 02:26

23 Q. Did Somerset actually manufacture for 02:26

24 sale and distribution solid oral dose 02:26

25 pharmaceutical products? 02:26

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1 A. Yes. 02:26

2 Q. What products? 02:26

3 A. Primarily Eldepryl, Selegiline 02:26

4 hydrochloride, Parkinson, Alzheimer's. And we did 02:26

5 a lot of R&D with respect to those forms. 02:26

6 Q. So what was your role specifically 02:26

7 regarding the manufacture, the assembling of raw 02:26

8 material, its blending, its tableting, its 02:26

9 in-process testing, what was your role? 02:26

10 A. Our role was -- 02:26

11 Q. No. Your role. 02:26

12 A. My role? I was supervising the 02:26

13 analytical laboratory, R&D laboratory, and quality 02:26

14 control laboratory. 02:27

15 Q. So you would have supervised the QC lab 02:27

16 that did finished product testing on that drug? 02:27

17 A. In support of application developments 02:27

18 like ANDA. The QC lab that did release testing 02:27

19 was not at that facility. 02:27

20 Q. All right. And not under your 02:27

21 supervision. 02:27

22 A. Not for release testing, no. 02:27

23 Q. What did you do for UDL? 02:27

24 A. I was -- 02:27

25 Q. In 1994 and the first month of 1995. 02:27

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1 A. I was an analytical research chemist. 02:27

2 Q. So did you do finished product testing 02:27

3 on solid oral dose pharmaceutical products? 02:27

4 A. Yes. 02:28

5 Q. What products? 02:28

6 A. It's been such a long time, I can't 02:28

7 recall specifics without guessing. 02:28

8 Q. Well, did you do any testing on 02:28

9 Digitek? 02:28

10 A. No. 02:28

11 Q. Did you have anything to do with the 02:28

12 design or formulation of blister packs? 02:28

13 A. No. 02:28

14 Q. Who was your supervisor with UDL? 02:28

15 A. My last supervisor was Anita Runyon. 02:28

16 Q. Do you know if she's still with UDL? 02:28

17 A. UDL, no. 02:28

18 Q. Does UDL still have facilities in Largo, 02:28

19 Florida, to your knowledge? 02:28

20 A. To my knowledge, no. 02:28

21 Q. Do you have any special training in or 02:29

22 expertise in pharmacovigilance? 02:29

23 A. No. 02:29

24 Q. Have you worked in pharmacovigilance for 02:29

25 a pharmaceutical company? 02:29

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1	A.	No.	02:29
2	Q.	When you are called upon to consult in	02:29
3		the pharmaceutical industry, do you consult on	02:29
4		pharmacovigilance issues?	02:29
5	A.	No.	02:29
6	Q.	Do you ever -- do you have any special	02:29
7		training or expertise in FDA regulatory affairs?	02:29
8	A.	No.	02:29
9	Q.	Have you ever worked directly in the	02:29
10		quality assurance of the manufacturing side of the	02:29
11		production of a solid oral dose pharmaceutical	02:29
12		product?	02:29
13	A.	As a permanent employee?	02:29
14	Q.	Yes.	02:30
15	A.	No.	02:30
16	Q.	Have you been consulted on the QA	02:30
17		manufacturing side of solid oral dose	02:30
18		pharmaceutical production?	02:30
19	A.	I have been involved in those	02:30
20		discussions with QA personnel, yes.	02:30
21	Q.	And is this in your consulting role?	02:30
22	A.	It is.	02:30
23	Q.	How many times do you think you've done	02:30
24		that particular role over the years?	02:30
25	A.	Interacting with QA?	02:30

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1 Q. Directly involved with QA on the 02:30  
2 manufacturing side as opposed to the QC on the 02:30  
3 analytical chem side. 02:30

4 A. From a consulting standpoint? 02:30

5 Q. Yes. 02:30

6 A. The real number I couldn't give you an 02:30  
7 exact number, but most consulting tasks that I've 02:30  
8 done, you end up interacting with QA almost on a 02:31  
9 daily basis. 02:31

10 Q. Okay. When you've done your consulting, 02:31  
11 and when you were an employee in pharmaceutical 02:31  
12 businesses, was most of your GMP work regarding 02:31  
13 lab and lab equipment issues as opposed to 02:31  
14 manufacturing side issues? 02:31

15 A. A lot of my specialty is in the 02:31  
16 laboratory. In most cases the laboratory is -- 02:31  
17 ends up involved in manufacturing-related issues. 02:31  
18 They are usually discovered or potentially 02:31  
19 discovered in the laboratory first in my 02:31  
20 experience. 02:31

21 Q. Okay. I think my question was whether 02:31  
22 the bulk of your work either as a consultant or -- 02:31  
23 in the pharmaceutical business was on the lab side 02:31  
24 of GMPs as opposed to the manufacturing side, not 02:32  
25 whether there is some spillover. Is the bulk the 02:32

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1	lab side?	02:32
2	A. There's a lot of overlap, but, yes, the	02:32
3	bulk is in the lab.	02:32
4	Q. Have you ever had any publications about	02:32
5	extra-thick tablets?	02:32
6	A. No.	02:32
7	Q. Have you had any publications about	02:32
8	tablets of normal size but varying active	02:32
9	pharmaceutical ingredient?	02:32
10	A. Could you say that again, please.	02:32
11	Q. Have you had any publications --	02:32
12	A. Yes.	02:32
13	Q. -- about tablets of normal size but	02:32
14	varying active pharmaceutical ingredient?	02:32
15	A. I have a publication with respect to TLC	02:32
16	analysis of -- if I recall correctly; it's been a	02:32
17	long time -- API and tablets, that look at	02:32
18	different ingredients in there.	02:33
19	Q. But that's the lab analysis of tablets;	02:33
20	correct?	02:33
21	A. That's correct, yes.	02:33
22	Q. Not about the root cause of the problem	02:33
23	to begin with?	02:33
24	A. Actually, there's -- it does expand into	02:33
25	that.	02:33

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1 Q. Okay. 02:33

2 A. As I said, invariably things start out 02:33

3 in the lab and end up spilling over into the 02:33

4 manufacturing quality system. 02:33

5 Q. Are you a member of any organizations, 02:33

6 professional organizations? 02:33

7 A. I am. 02:33

8 Q. And which ones? 02:33

9 A. I have them listed here. Curiously 02:33

10 enough, I don't. 02:33

11 Q. So? 02:33

12 A. I -- 02:33

13 Q. What are you a member of? 02:33

14 A. I am a member of -- if my memory is not 02:33

15 complete, I apologize, but I have been a member of 02:33

16 the ACS. 02:34

17 Q. No, now. 02:34

18 A. Now I'm a member of the ACS. I have 02:34

19 been a member for a long time. 02:34

20 Q. The American Chemical Society? 02:34

21 A. It is. American Association of 02:34

22 Pharmaceutical Scientists, also American Society 02:34

23 of Quality. 02:34

24 Q. Do you know whether any of those 02:34

25 organizations have ethical guidelines regarding 02:34

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1 testimony in court cases? 02:34

2 A. I don't know. 02:34

3 Q. Does your website have a section about 02:34  
4 your core competencies? 02:34

5 A. I'd have to go back and pull up the 02:34  
6 page. It's been a while. 02:34

7 Q. I wrote that in quotes so I may have 02:34  
8 quoted it directly. 02:34

9 A. Okay. 02:34

10 Q. If that -- 02:34

11 A. One doesn't normally visit your own 02:34  
12 website. 02:34

13 Q. One should. 02:34

14 A. Yeah. 02:34

15 Q. If one -- if there is a section on core 02:34  
16 competencies, does it say anything about 02:34  
17 manufacturing in there? 02:34

18 A. I don't recall. 02:35

19 Q. All right. Now, you have written a book 02:35  
20 apparently about validating chromatographic 02:35  
21 methods; is that right? 02:35

22 A. That's correct. 02:35

23 Q. Is that book still available? 02:35

24 A. It is. 02:35

25 Q. It was published in '06; is that right? 02:35



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1 A. If that's what it says here on the 02:35  
2 resume, that would be the year. 02:35

3 Q. Have they asked you to do a second 02:35  
4 edition? 02:35

5 A. Not yet. 02:35

6 Q. Is it universally accepted that methods 02:35  
7 used in forensic work have to undergo validation? 02:35

8 A. Forensic work? 02:35

9 Q. Yeah. 02:35

10 A. I'm a not familiar with forensic 02:35  
11 analysis. 02:35

12 Q. Is it universally accepted in the 02:35  
13 pharmaceutical business that the test methods for 02:35  
14 things like finished product testing have to go 02:35  
15 through validation? 02:35

16 A. Absolutely. 02:35

17 Q. Have you ever done assay or content 02:36  
18 uniformity testing on Digoxin? 02:36

19 A. No. 02:36

20 Q. Have you ever developed an assay or 02:36  
21 content uniformity method for testing any solid 02:36  
22 oral dose pharmaceutical product? 02:36

23 A. Say that again. I'm sorry. I lost 02:36  
24 you. I was still thinking about the last 02:36  
25 question. 02:36

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1	Q.	Have you ever developed and validated a	02:36
2		method to test for the potency of any solid oral	02:36
3		dose pharmaceutical product?	02:36
4	A.	I have been involved in that.	02:36
5	Q.	How many times?	02:36
6	A.	Solid oral doses?	02:36
7	Q.	Yeah.	02:36
8	A.	About three or four I would say.	02:36
9	Q.	If you assume that you were going to	02:37
10		develop a method to test the potency of a tablet,	02:37
11		and you had never done that before --	02:37
12	A.	Uh-huh.	02:37
13	Q.	-- okay, how long do you think it would	02:37
14		take you to develop and validate the method?	02:37
15	A.	From scratch?	02:37
16	Q.	From scratch.	02:37
17	A.	A new chemical entity?	02:37
18	Q.	No, a common chemical entity but you've	02:37
19		never done it before.	02:37
20	A.	It really depends on the chemistry of	02:37
21		the molecule.	02:37
22	Q.	Give me the short side.	02:37
23	A.	Short side?	02:38
24	Q.	Yeah.	02:38
25	A.	Develop a method?	02:38

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1	Q.	Yeah.	02:38
2	A.	And validate it?	02:38
3	Q.	Yeah.	02:38
4	A.	This is when I go back and look at my	02:38
5		book. Approximately, from scratch?	02:38
6	Q.	Yes, sir.	02:38
7	A.	Approximately six to nine months from	02:38
8		scratch.	02:38
9	Q.	So if somebody came to you and said this	02:38
10		is a test that from the time of starting the	02:38
11		validation, running the standards, the blanks, and	02:38
12		the sample that you were going to test, total of	02:38
13		two hours, that would be inconsistent with your	02:38
14		experience?	02:38
15	A.	Validation?	02:38
16	Q.	Yes, sir.	02:38
17	A.	That's not a validation.	02:38
18	Q.	Okay. When you talked earlier, you were	02:38
19		referring to something about chromatography. Is	02:38
20		the -- is the -- what does it mean if the results	02:39
21		of the test exceed the range of your standard?	02:39
22		What does it do to the validity of your test?	02:39
23	A.	Please bear with me on this.	02:39
24	Q.	Yeah.	02:39
25	A.	I'm not sure I understand what you're	02:39

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1 asking. 02:39

2 Q. Well, I'm not an analytical chemist so 02:39

3 I'm doing the best I can from memory. When you 02:39

4 run the standard, you get a range, don't you? 02:39

5 A. A range? 02:39

6 Q. Yeah, a range for what the results ought 02:39

7 to be on the standards? 02:39

8 A. Now, in the pharmaceutical industry with 02:39

9 respect to assay, you don't do a set of 02:39

10 standards. You do one standard. 02:39

11 Q. Okay. 02:39

12 A. And you come up with an acceptance 02:39

13 criteria up-front, through establishing 02:39

14 suitability of the methodology and the equipment 02:39

15 and then you confirm in most cases whether the 02:39

16 standards that you have in there are suitable for 02:40

17 intended use as the run is established. 02:40

18 Q. And aren't your results supposed to be 02:40

19 within the range of your standards? 02:40

20 A. Yeah, I am using term range -- 02:40

21 Q. Results of the actual test. 02:40

22 A. The standard is used to determine the 02:40

23 amount in the sample that you're analyzing, if 02:40

24 that's what you mean. 02:40

25 Q. Then if you test the sample and it 02:40

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1 exceeds the range of your standard, what does it 02:40  
2 do with the validity? 02:40  
3 A. It exceeds the amount? 02:40  
4 Q. Yeah. 02:40  
5 A. Then the -- the result initially is 02:40  
6 suspect. 02:40  
7 Q. Okay. 02:40  
8 A. And then it requires an investigation. 02:40  
9 Q. All right. 02:40  
10 THE WITNESS: Can we take a break, 02:40  
11 please? 02:40  
12 MR. MORIARTY: Sure. 02:40  
13 THE VIDEOGRAPHER: The time is 2:43 p.m. 02:40  
14 We're going off the record briefly. 02:41  
15 (Short break) 02:46  
16 THE VIDEOGRAPHER: The time is now 02:46  
17 2:50 p.m. We are back on the record. 02:47  
18 BY MR. MORIARTY: 02:47  
19 Q. Earlier we were talking about process 02:47  
20 validation and you mentioned something about bulk 02:47  
21 stability hold time studies; okay? 02:47  
22 A. Uh-huh. 02:47  
23 Q. Now, I don't have the 438 regarding that 02:48  
24 but I have the Exhibit 171, November 9th, 2007, 02:48  
25 EIR from FDA; okay? 02:48

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1	A.	Okay.	02:48
2		MR. FITZPATRICK: I'm sorry. What was	02:48
3		the date?	02:48
4		MR. MORIARTY: The letter I have is	02:48
5		September -- November 9th. November 9th,	02:48
6		2007; okay? And it says:	02:48
7		"We are enclosing a copy of the	02:48
8		establishment inspection report for the	02:48
9		inspection conducted at your premises at	02:48
10		location on September 5th, 2007, et al.," and	02:48
11		then in here it addresses some earlier 483s;	02:48
12		okay?	02:48
13		THE WITNESS: Okay.	02:48
14	BY MR. MORIARTY:		02:48
15	Q.	I want you to look at observation number	02:48
16	7 --		02:49
17	A.	Okay.	02:49
18	Q.	-- in this EIR.	02:49
19	A.	Okay.	02:49
20	Q.	Does that -- does observation seven	02:49
21		correlate with what you were talking about before	02:49
22		about this bulk stability hold time issue?	02:49
23	A.	To save time, do you recall what my A	02:49
24		number was that went with it when I looked at	02:49
25		this?	02:49

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1	MR. ANDERTON: Yeah, A25.	02:49
2	THE WITNESS: 25?	02:50
3	MR. ANDERTON: Yes, page 41 of your	02:50
4	report.	02:50
5	THE WITNESS: Great. Thank you.	02:50
6	MR. ANDERTON: Actually, the comment is	02:50
7	on page 42.	02:50
8	THE WITNESS: Got you. Thank you.	02:50
9	I believe my information came directly	02:50
10	from the warning label.	02:50
11	BY MR. MORIARTY:	02:50
12	Q. I'm asking you if this EIR discussion	02:50
13	observation seven correlates to that warning	02:50
14	letter.	02:50
15	A. I don't think so. I think that that was	02:51
16	another observation from the previous inspection	02:51
17	that was in 17 November, 2006, from what it	02:51
18	looks.	02:51
19	If we go to my reference where I talk about --	02:51
20	hold on a second -- let's see. Oh, one page	02:51
21	down. Excuse me. I misspoke. I was one line off	02:51
22	in my own paper. Warning letter was issued 10	02:51
23	July for the August 2006 inspection of Little	02:51
24	Falls. So my reference here is with respect to a	02:51
25	warning letter for an inspection that was 10 July	02:51

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1 to 10 August 2006. And this is 5 September to 28 02:52

2 September, 2007. So those are two different 02:52

3 things. 02:52

4 So this is an additional observation with 02:52

5 respect to problems potentially with bulk hold 02:52

6 times. 02:52

7 Q. Go back to page 25 of 40 in Exhibit 02:52

8 171. It bears Bates page 505285. 02:52

9 A. Okay. All right. Page 25 of 40. 02:52

10 Q. Go to the top. It says "voluntary 02:52

11 corrections." Do you see that? 02:52

12 A. I do see that. 02:52

13 Q. "Corrections to the previous FDA 483 02:52

14 were reviewed with Wanda Eng, director of 02:52

15 corporate compliance for Actavis U.S. The 02:52

16 previous 483 observations and the associated 02:52

17 corrections, included below." 02:52

18 A. Okay. 02:52

19 Q. Do you see that? 02:52

20 A. I do see that. 02:52

21 Q. All right. So this observation seven is 02:52

22 at least referring to the bulk stability data; 02:53

23 correct? 02:53

24 A. I'm not sure. I'm not trying to be 02:53

25 difficult here. I'm just not sure. 02:53



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1 Q. Page 31 of 40, observation seven says 02:53  
2 the stability data recorded as that of bulk 02:53  
3 stability hold time studies are actually obtained 02:53  
4 from the testing of the following packaged 02:53  
5 finished products. 02:53

6 Do you see that? 02:53

7 A. I do. 02:53

8 Q. Okay. 02:53

9 A. I'm just trying to make sure we're 02:53  
10 talking about the same one, or is this an 02:53  
11 additional observation from the -- this current 02:53  
12 inspection? 02:53

13 Q. Well, let's talk about this one. 02:53

14 A. Okay. "This one" being this observation 02:53  
15 right here? 02:53

16 Q. Right here. Observation seven. 02:53

17 A. Okay, okay. 02:53

18 Q. Digitek isn't mentioned, is it? 02:53

19 A. The corrections here would indicate that 02:53  
20 "All of the bulk hold time studies have been 02:54  
21 repeated on each of the above-listed products at 02:54  
22 time points beyond three months as immediate 02:54  
23 corrective action." 02:54

24 So based on that statement, it appears that 02:54  
25 that bulk hold time stability study -- for 02:54

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1	whatever reason it's blacked out, which we don't	02:54
2	know what it is, and I'm not sure why it's blacked	02:54
3	out. Do we know?	02:54
4	Q. Let's deal with one question at a time.	02:54
5	A. Okay. That --	02:54
6	Q. It was remediated and resolved to the	02:54
7	satisfaction of FDA, was it not?	02:54
8	A. For these three products.	02:55
9	Q. Yes; right.	02:55
10	A. For these three products, yes.	02:55
11	Q. And Digitek is not even mentioned in	02:55
12	observation seven, is it?	02:55
13	A. Unless it was blacked out.	02:55
14	Q. Well, we don't black out Digitek in the	02:55
15	Digitek litigation; okay?	02:55
16	A. Okay, okay.	02:55
17	Q. So Digitek isn't mentioned?	02:55
18	A. It is not, no.	02:55
19	Q. Do you subscribe to or regularly review	02:55
20	any journals in the pharmaceutical industry?	02:55
21	A. And, again, I'm not trying to be	02:55
22	difficult. How are you -- journals. What do you	02:55
23	mean by a journal?	02:55
24	Q. Like any journal whether it's online or	02:55
25	not. A scholarly collection of publications by --	02:56

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1 A. Peer-reviewed journal? 02:56

2 Q. Yes. 02:56

3 A. I will pull up articles that are 02:56

4 pertinent but as far as reading a journal, no. 02:56

5 Q. Well, how do you know there are articles 02:56

6 out there that are pertinent? 02:56

7 A. FDA notices from their websites and my 02:56

8 trade magazines have references to articles, and I 02:56

9 keep current by my trade publications that come 02:56

10 out sometimes every two weeks that funnel you back 02:56

11 to the things that are important. 02:56

12 Q. What trade publications do you get? 02:56

13 A. The AAPS magazine, CEN news. 02:56

14 Q. What is AAPS? 02:56

15 A. That's the American Association of 02:56

16 Pharmaceutical Scientists. 02:56

17 Q. Okay. And are there any other ones you 02:56

18 get? 02:56

19 A. Chemical and Engineering News, which is 02:56

20 a publication of the American Chemical Society. 02:56

21 Q. Anything else? 02:56

22 A. American Society Quality periodically 02:56

23 puts out notices with respect to compliance 02:56

24 issues. They also have a magazine that comes out 02:57

25 like once a month, too, that references that. And 02:57

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1 I read books. 02:57

2 Q. Do you know what the FDA's application 02:57

3 integrity policy is? 02:57

4 A. Never heard of it. 02:57

5 Q. In your experience, are FDA inspectors 02:57

6 regularly on the lookout for falsified data in 02:57

7 submissions like NDAs and ANDAs as well as routine 02:57

8 reporting? 02:57

9 A. I think that's one of the things they 02:57

10 are cognizant of. 02:57

11 Q. Are the -- if FDA detects document 02:57

12 integrity problems, is their response typically 02:57

13 swift and severe? 02:58

14 A. Swift no doubt. It depends on the 02:58

15 document problem. Obviously there are different 02:58

16 flavors of documentation problems. 02:58

17 Q. Do you have experience with this topic? 02:58

18 A. Yeah. 02:58

19 Q. Do you consider yourself an expert in 02:58

20 it? 02:58

21 A. In FDA addressing documentation issues? 02:58

22 Q. Right. 02:58

23 A. Yes. 02:58

24 Q. I mean where they suspect that the 02:58

25 documents are falsified, do you have experience in 02:58

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1 that? 02:58

2 A. I have had direct experience of that in 02:58

3 the last eight months. 02:58

4 Q. All right. Now nowhere in your report 02:58

5 did I see you render any opinion that Actavis's 02:58

6 documents were falsified or had questionable 02:58

7 integrity. 02:58

8 Am I correct about that? 02:58

9 A. I don't believe there is any statement 02:59

10 to that effect in the report. 02:59

11 Q. And can you point me to any FDA 483 02:59

12 warning letter or other regulatory document that 02:59

13 cites Actavis for having suspicious or falsified 02:59

14 documentation? 02:59

15 A. If I'm not mistaken -- and we have to go 02:59

16 back and look -- but there should be several 02:59

17 notations with respect not documenting things as 02:59

18 they occur, which would be considered a 02:59

19 documentation issue. 02:59

20 Q. I'm talking about falsifying. 02:59

21 A. Falsifying? Falsifying, no. 02:59

22 Q. That's what I'm asking about. 02:59

23 A. Falsifying is very difficult to assess 02:59

24 unless you're at the facility as well, so... 02:59

25 Q. Well, FDA was at the facility on several 02:59

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1 occasions in '06, '07 and '08, were they not? 02:59

2 A. Yes. 03:00

3 Q. Does an ANDA contain a -- let me 03:00

4 withdraw that. 03:00

5 How much are you charging for your time to 03:00

6 review materials in this consulting work? 03:00

7 A. As strange as it sounds, my bookkeeper 03:00

8 does the billing. I can't honestly answer that 03:00

9 question what the billing rate is. We negotiated 03:00

10 a rate, it's in an e-mail, there was some 03:00

11 additional discussions, but I don't know what's 03:00

12 going on in the invoice to be honest with you. 03:00

13 Q. What's the rate? 03:00

14 A. Again, as strange as it sounds, I have 03:00

15 to go back and look at the specific e-mail. 03:01

16 Q. You don't want me hauling your wife down 03:01

17 here to talk about this. 03:01

18 A. Oh, no, no. 03:01

19 Q. Do you know what the total amount billed 03:01

20 and received for your company to date is on this 03:01

21 consulting arrangement? 03:01

22 A. Not off the top of my head, no. 03:01

23 Q. Is it over \$20,000? 03:01

24 A. I would say that's a fair assessment. 03:01

25 Q. Is it over \$35,000? 03:01

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1 A. I'd say that's a fair assessment. 03:01

2 Q. I would like you to find out what your 03:01

3 rate is and what the billings and receipts are to 03:01

4 date; okay? 03:01

5 A. Okay. 03:01

6 Q. Because we're not going to finish 03:01

7 today. So somebody gets to come back and question 03:01

8 you on another day about those things; okay? 03:01

9 A. Okay. 03:01

10 Q. Now, when a company is on consent 03:01

11 decree, isn't it required that they comply with 03:01

12 GMPs? 03:02

13 A. If a company gets placed under a consent 03:02

14 decree, if it's with respect -- because there are 03:02

15 several different types of consent decrees that go 03:02

16 outside the GMPs -- the company goes into the 03:02

17 voluntary agreement of consent decree if they've 03:02

18 had chronic and sustained problems with respect to 03:02

19 compliance with the GMPs, in my experience. 03:02

20 Q. Are you done with your answer? 03:02

21 A. Yes, sir. 03:02

22 MR. MORIARTY: That wasn't my question. 03:02

23 THE WITNESS: I'm sorry. 03:02

24 BY MR. MORIARTY: 03:02

25 Q. My question was when you're on consent 03:02

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1 decree, aren't you required to comply with GMPs? 03:02

2 A. You are required to comply with GMPs 03:02

3 whether you are on consent decree or not. 03:02

4 Q. Well, what does the FDA do when you are 03:02

5 on consent and you are found not to be in 03:02

6 compliance with GMPs? 03:02

7 A. Even if you are under consent decree, 03:02

8 the agency continues to audit and make findings 03:03

9 and they continue on outside of that agreement, 03:03

10 just like they would normally. 03:03

11 Q. All right. So you know that when Amide 03:03

12 came off consent decree in 2000, 2002, somewhere 03:03

13 in there, it was because of sustained compliance 03:03

14 with GMPs; correct? 03:03

15 A. They had demonstrated they had fulfilled 03:03

16 the obligations of the consent decree. 03:03

17 Q. I would like you to look at Exhibit 22, 03:04

18 please. Do you know whether you have seen this 03:04

19 letter before? It's a warning letter dated 03:04

20 January 9th, 2007. 03:04

21 A. Okay. 03:05

22 Q. Do you know whether you've seen it 03:05

23 before? 03:05

24 A. Not without looking at my list, no. 03:05

25 Q. Okay. 03:05



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1 A. Some warning letters weren't available. 03:05

2 Q. I want you to go to the second to last 03:05

3 page of this document. The Bates numbers are a 03:05

4 little bit cut off, but it's 2883 something. 03:05

5 A. Something, got you. 03:05

6 Q. Do you see that? 03:05

7 A. I do, sir. 03:05

8 Q. In the last paragraph -- 03:05

9 A. Uh-huh. 03:05

10 Q. -- the FDA said: 03:05

11 "We feel that to provide such assurance, your 03:05

12 firm should promptly initiate an audit program by 03:05

13 a third-party having appropriate cGMP expertise to 03:05

14 provide assurance that all marketed lots of drug 03:06

15 products that remain within expiration have their 03:06

16 appropriate identity, strength, quality and 03:06

17 purity." 03:06

18 Do you see that? 03:06

19 A. Where is that? I missed it. 03:06

20 MR. KERENSKY: It's last sentence of the 03:06

21 paragraph. 03:06

22 THE WITNESS: The last sentence of the? 03:06

23 MR. KERENSKY: Last paragraph. 03:06

24 THE WITNESS: Last paragraph; okay. I'm 03:06

25 sorry. "We feel that to provide such 03:06

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1 assurance, your firm should promptly 03:06

2 initiate" -- yes, I see that. 03:06

3 BY MR. MORIARTY: 03:06

4 Q. Okay. 03:06

5 A. Yes. 03:06

6 Q. Do you know what Actavis did in response 03:06

7 to Exhibit 22? 03:06

8 A. Specifically, no. However, I know that 03:06

9 consulting firms were involved at some point. 03:06

10 Q. Do you know what consulting firms? 03:07

11 A. With respect to this specific warning 03:07

12 letter? 03:07

13 Q. Yeah. 03:07

14 A. I can't tell you that. 03:07

15 Q. Do you know anything about Quantic 03:07

16 Regulatory Services? 03:07

17 A. I do. 03:07

18 Q. What do you know about them? 03:07

19 A. I have worked as subcontractor for them. 03:07

20 Q. Are they considered to be a reliable 03:07

21 firm in the pharmaceutical field? 03:07

22 A. They are to me, yes. 03:07

23 Q. Well, FDA is specifically saying your 03:07

24 firm should initiate an audit program by a 03:07

25 third-party having appropriate cGMP expertise. Is 03:07

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1 Quantic Regulatory Services considered to have 03:07

2 appropriate cGMP expertise? 03:07

3 A. Yes. 03:07

4 Q. Okay. Have you ever seen Exhibit 23? 03:07

5 A. Yes. 03:08

6 Q. All right. Exhibit 23 is a letter dated 03:08

7 December 24th, 2007, to FDA from Actavis; correct? 03:08

8 A. Yes. 03:08

9 Q. Enclosing reports from Quantic; is that 03:08

10 right? 03:08

11 A. Right, that appears to be. 03:09

12 Q. Okay. Now, I assume you didn't work for 03:09

13 Quantic on this project, did you? 03:09

14 A. No, sir. 03:09

15 Q. So if we go to -- do you know how many 03:09

16 Digitek batches Quantic looked at? Batch records 03:09

17 I should say. 03:09

18 A. No. 03:09

19 Q. Now, Quantic specifically found in its 03:09

20 batch review at page 1867209. 03:10

21 A. I have that page. 03:10

22 Q. All right. If you look sort of right in 03:10

23 the middle of the page they say: 03:10

24 "Based upon this review, it is QRS's opinion 03:10

25 that except as set forth below, the batch records 03:10

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1 reviewed did not contain non-conformances or 03:10  
2 deficiencies that are likely to have had a 03:10  
3 material, adverse impact on the identity, 03:11  
4 strength, quality or purity of such other 03:11  
5 batches." 03:11

6 Okay? 03:11

7 Now do you have any data available to you on 03:11  
8 which you could conclude that you disagree with 03:11  
9 QRS about the batch records that they reviewed? 03:11

10 A. The batch records they reviewed? 03:11

11 Q. Correct. 03:11

12 A. No. 03:11

13 Q. Do you know how many of the Digitek 03:11  
14 batches that they reviewed -- the Digitek batch 03:11  
15 records that they reviewed were recalled Digitek 03:11  
16 batches? 03:11

17 A. I'm sorry. Say that again. 03:11

18 Q. Do you know how many of them were 03:11  
19 recalled Digitek batches? 03:11

20 A. No. 03:11

21 Q. If just assuming that QRS's conclusion 03:11  
22 was correct that they have reliably confirmed the 03:12  
23 identity, strength, quality, and purity of the 03:12  
24 batch records that reviewed; okay? 03:12

25 A. That they reviewed. 03:12

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1 Q. That they reviewed, that would mean that 03:12  
2 those batches were not even adulterated; is that 03:12  
3 correct? 03:12

4 A. What they reviewed was, correct. That's 03:12  
5 what you can say. The batch record. And 03:12  
6 apparently here laboratory testing represents part 03:12  
7 of that, which may or may not show the product's 03:12  
8 adulterated. 03:12

9 Q. So one way that the FDA -- well, do you 03:12  
10 have any evidence that the FDA accepted or 03:12  
11 rejected this remediation of that part of the 03:13  
12 January 2007 warning letter? 03:13

13 A. Yesterday was the first time I saw this, 03:13  
14 so I have nothing other than this. 03:13

15 Q. All right. Well, would it be correct -- 03:13  
16 I would I be correct in assuming that batch 03:13  
17 records -- batch record reviews when conducted as 03:13  
18 QRS did would be one way to determine if batches 03:13  
19 are adulterated? 03:13

20 A. It's -- it is a measure to take and to 03:13  
21 go back to try to determine, potentially. 03:13

22 Q. Okay. Is there some reason why you 03:13  
23 didn't review batch records? Let's assume you 03:13  
24 reviewed one or two. 03:13

25 A. Reviewed the ones in the ANDA. 03:13

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1 Q. Because you don't remember. Is there 03:13  
2 some reason why you didn't review batch records 03:13  
3 from '06, '07, and '08? 03:13

4 A. I reviewed the documentation that I was 03:13  
5 requested to review and provided to me in addition 03:14  
6 to the ones I was asking for. That's it. 03:14

7 Q. I understand that. 03:14

8 A. Yeah. 03:14

9 Q. But you had access to an online 03:14  
10 repository. Yet all these documents -- 03:14

11 A. I did not have access to all the 03:14  
12 documents. They were selectively provided me in a 03:14  
13 folder. 03:14

14 Q. Did you ask to review batch records? 03:14

15 A. I provided a list of things that I 03:14  
16 asked. I'd have to look at that to determine 03:14  
17 whether I asked for batch records. 03:14

18 Q. Do you have that list here? Because we 03:14  
19 asked in the notice of deposition -- well, we'll 03:14  
20 get into that at some point. 03:14

21 A. Right. 03:14

22 Q. That you bring all your correspondence? 03:14

23 A. Yes, I got -- I have it on a hard 03:14  
24 drive. All my e-mail communications is on a hard 03:14  
25 drive. 03:14

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1	Q.	So you believe that in an e-mail you	03:14
2		corresponded to some Plaintiffs' lawyers, Fred,	03:14
3		Meghan, whoever it happened to be --	03:14
4	A.	Uh-huh.	03:15
5	Q.	-- that you that you wanted to see	03:15
6		documents.	03:15
7	A.	Yes.	03:15
8	Q.	And do you remember now whether they	03:15
9		supplied all the documents you asked for?	03:15
10	A.	I'm not sure. I'd have to look at the	03:15
11		list to see what was provided.	03:15
12	Q.	Do you remember now whether batch	03:15
13		records was some of things that you asked for?	03:15
14	A.	I can't tell you with certainty, no, I	03:15
15		can't.	03:15
16	Q.	And do you have that hard drive with	03:15
17		you?	03:15
18	A.	I do.	03:15
19	Q.	But it's on your laptop or did you --	03:15
20	A.	It's external.	03:15
21	Q.	Put it on a thumb drive?	03:15
22	A.	It's an external drive.	03:15
23	Q.	Is it like a little thumb drive?	03:15
24	A.	A Passport hard drive.	03:15
25	Q.	Is that a copy of the hard drive or is	03:15

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1 that the hard drive? 03:15

2 A. That is the hard drive. When I first 03:15

3 started doing the work, since I've never done it 03:15

4 before, their recommendation was that everything 03:15

5 with respect to this go on that hard drive. 03:15

6 Q. Okay. Certainly -- I mean we're going 03:16

7 to need at some point access to that hard drive; 03:16

8 okay? 03:16

9 A. Sure. 03:16

10 Q. So don't delete anything. 03:16

11 A. Oh, no, no. 03:16

12 Q. We'll just have to figure out 03:16

13 logistically how we can do that. 03:16

14 A. Okay. 03:16

15 Q. How many times have you worked with 03:16

16 Quantic Regulatory Services? 03:16

17 A. As far as consulting jobs go? 03:16

18 Q. Yes, sir. 03:16

19 A. Let's see. I have worked on the Wyeth 03:16

20 consent decree, the Schering Plough consent 03:16

21 decree, and I believe one other. To the best of 03:16

22 my knowledge three. 03:16

23 Q. Have you worked with QRS in some other 03:17

24 capacity besides consulting? 03:17

25 A. No. 03:17



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1 Q. When you have worked as a consultant for 03:17  
2 Quantic Regulatory Services, have you done batch 03:17  
3 record reviews for them or for other companies and 03:17  
4 other products? 03:17

5 A. No. And if I could, please, when you 03:17  
6 say Quantic Regulatory Services, there's -- if I'm 03:17  
7 not mistaken there's like three entities of 03:17  
8 Quantic. One is the regulatory services, one 03:17  
9 Quantic, and there's another one, depending on 03:17  
10 what the job is covered by. 03:17

11 So to answer that question accurately, I'm not 03:17  
12 sure which one we're referring to, which one of 03:17  
13 those business entities, just to be clear. 03:17

14 Q. How many companies -- how many other 03:18  
15 companies that you worked for in the 03:18  
16 pharmaceutical industry were at one point on 03:18  
17 consent decree? 03:18

18 A. As a permanent employee worked for? 03:18

19 Q. Yeah. 03:18

20 A. At one point? 03:18

21 Q. Yeah. 03:18

22 A. To my knowledge, none of the companies. 03:18

23 Q. What about in your consulting 03:18  
24 arrangements? How many of the companies have been 03:18  
25 on consent decree at some point? 03:18

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1 A. That I know of? 03:18

2 Q. Yeah. 03:18

3 A. Two. 03:18

4 Q. And Wyeth was one. Are you able to tell 03:18  
5 me who the other one is? 03:18

6 A. Schering Plough. 03:18

7 Q. When you were working with those 03:18  
8 companies regarding consent decrees, did you tell 03:18  
9 them that a consent decree was because of a 03:19  
10 repeated and persistent non-compliance with the 03:19  
11 law? 03:19

12 A. That was not my function to tell the 03:19  
13 companies that. So me personally, no. 03:19

14 Q. Did you believe when you were consulting 03:19  
15 with them that they were on consent decree because 03:19  
16 of repeated, persistent non-compliance with the 03:19  
17 law? 03:19

18 MR. KERENSKY: Wait a minute. I want to 03:19  
19 caution you there. 03:19

20 THE WITNESS: Yeah. 03:19

21 MR. KERENSKY: We're on the same page. 03:19  
22 Because you're now asking him to say 03:19  
23 something, a conclusion he drew based on stuff 03:19  
24 he knew about while working there and working 03:19  
25 with them, which may be covered by the 03:19

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1 confidentiality agreements he has. 03:19

2 THE WITNESS: All I know, if I could, is 03:19

3 that these companies all post the consent 03:19

4 decree and the letter by quality assurance and 03:19

5 management on bulletin boards so everybody can 03:20

6 see what it's all about. That's part of the 03:20

7 function. 03:20

8 BY MR. MORIARTY: 03:20

9 Q. I understand that. But do you -- I mean 03:20

10 you have said that my client or pharmaceutical 03:20

11 companies in general go on consent decree for 03:20

12 repeated, persistent non-compliance with the law, 03:20

13 and I'm trying to find out whether that is a 03:20

14 phrase that you're applying only to Actavis or 03:20

15 whether you also apply it to companies that you 03:20

16 consult with in the non-litigation world. 03:20

17 A. Again, I'm not -- 03:20

18 THE VIDEOGRAPHER: Five minutes. 03:20

19 THE WITNESS: Again, I'm not sure I 03:20

20 really understand the gist of the question. I 03:20

21 apologize. 03:20

22 BY MR. MORIARTY: 03:21

23 Q. Okay. At page 8 of your report. 03:21

24 A. Okay. 03:21

25 Q. It says: 03:21

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1 "It should be noted in my experience consent 03:21  
2 decrees are not common and mostly occur when a 03:21  
3 company has shown repeated and persistent 03:21  
4 non-compliance with the law." 03:21

5 Do you see that? 03:21

6 A. Yes, I do. 03:21

7 Q. All right. What I'm trying to find out 03:21  
8 about, Dr. Bliesner, is whether you are just 03:21  
9 making a comment about my client or whether that 03:21  
10 is your opinion about pharmaceutical companies and 03:21  
11 the consent decree generally. 03:21

12 A. Yes. 03:21

13 Q. Yes which? 03:21

14 A. They -- that it takes an awful lot to 03:21  
15 get a consent decree. It's a progress of numerous 03:21  
16 483s, warning letters in most circumstances. 03:21  
17 Sometimes they go directly to it. There's 03:21  
18 numerous 483s, warning letters, and then it gets 03:21  
19 to the point where the agency says we don't have 03:21  
20 enough resources anymore to manage this. Let's go 03:21  
21 into an agreement. 03:22

22 Q. And have you ever consulted with a 03:22  
23 pharmaceutical company about a product that was in 03:22  
24 litigation, product liability litigation? 03:22

25 A. Consulted specifically about the product 03:22

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1	liability?	03:22
2	Q. Yeah.	03:22
3	A. No.	03:22
4	Q. Does the ANDA for any product, including	03:22
5	Digitek, contain the formula for the active	03:22
6	ingredients and how they are to be blended?	03:22
7	A. The formula, yeah. The combination of	03:22
8	excipients and active.	03:22
9	Q. Yes.	03:22
10	A. In my experience they do contain that.	03:22
11	Q. And presumably they have to be mixed in	03:22
12	appropriate proportions in order to comply with	03:22
13	the formula; correct?	03:22
14	A. They need to follow their manufacturing	03:23
15	steps in order to -- to come up with a proper	03:23
16	dosage for them, whether it involved mixing or	03:23
17	whatever.	03:23
18	Q. And those steps are approved by the FDA;	03:23
19	correct?	03:23
20	A. Those steps are in the application. If	03:23
21	the application is approved and the FDA has found	03:23
22	the information in the application acceptable.	03:23
23	THE VIDEOGRAPHER: We should definitely	03:23
24	change tapes.	03:23
25	The time is 3:26 p.m. We're going off	03:23

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1	the record.	03:23
2	THE VIDEOGRAPHER: The time is now	03:34
3	3:37 p.m. We are back on the record. This is	03:34
4	the beginning of tape six.	03:34
5	BY MR. MORIARTY:	03:34
6	Q. Okay. We were asking before the break	03:34
7	about formulas; okay? Have you seen any 483 or a	03:34
8	warning letter, any sort of citation or sanction	03:35
9	by the FDA on Actavis for any problem with the	03:35
10	actual mixing of the ingredients? In other words,	03:35
11	using inappropriate proportions of ingredients?	03:35
12	A. Proportions?	03:35
13	Q. Yes.	03:35
14	A. Not that I recall.	03:35
15	Q. So you don't have any evidence that any	03:35
16	Digitek batch started with too much active	03:35
17	pharmaceutical raw ingredient?	03:35
18	A. I don't have any evidence.	03:35
19	Q. You are aware that Actavis tests every	03:36
20	batch at the blend stage.	03:36
21	A. Every batch at the blend stage?	03:36
22	Q. Yeah.	03:36
23	A. I don't have information that I've seen	03:36
24	that confirms or denies that.	03:36
25	Q. Okay.	03:36

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1 In your work in the pharmaceutical industry -- 03:36  
2 not in your consulting work -- how much contact 03:36  
3 did you have with blend uniformity sampling or 03:36  
4 testing? 03:36  
5 A. Testing. 03:36  
6 Q. So not sampling? 03:36  
7 A. No. 03:36  
8 Q. Not the core sampling? 03:36  
9 A. No. 03:36  
10 Q. But you did have some with testing? 03:36  
11 A. Yes. 03:36  
12 Q. And typically when a company does blend 03:36  
13 sampling from a dry blend batch, how many core 03:36  
14 samples do they take and submit to a QC lab for 03:37  
15 analysis? 03:37  
16 A. That varies. It's not a set thing. 03:37  
17 Q. From your reading -- 03:37  
18 A. And it's always a battle. 03:37  
19 Q. Why is it a battle? 03:37  
20 A. Because the lab always wants less 03:37  
21 samples and the validation people want more 03:37  
22 samples, and they go back and forth to try to 03:37  
23 determine number of samples to be sent to be 03:37  
24 analyzed. It's a very big challenge. 03:37  
25 Q. Why does the lab want less samples? 03:37

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1 A. Because usually you're doing their 03:37  
2 release testing on top of process validation, so 03:37  
3 it's doubling their workload. 03:37

4 Q. From your reading in pharmaceutical 03:37  
5 publications over time, have you found that blend 03:37  
6 uniformity sampling and testing in general is a 03:37  
7 controversial subject? 03:37

8 A. Controversial? 03:37

9 Q. Yes, sir. 03:37

10 A. I wouldn't use the word controversial. 03:38

11 Q. Have there been efforts by 03:38  
12 pharmaceutical companies to have the FDA eliminate 03:38  
13 the requirement of blend uniformity sampling 03:38  
14 because it's notoriously difficult to do and 03:38  
15 control well? 03:38

16 A. I know that Actavis in some of their 03:38  
17 documentation make reference to try to stop blend 03:38  
18 uniformity testing. 03:38

19 Q. Do you know about any other company? 03:38

20 A. Specifically that I've been involved 03:38  
21 with? 03:38

22 Q. Actually I mean generally. 03:38

23 A. Generally. 03:38

24 Q. Your general knowledge of the industry. 03:38

25 A. Blend uniformity as I said is always a 03:38



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1 challenge anyway, so... 03:38

2 Q. Okay. So can you point to me any 03:38

3 document where the FDA cited or warned the company 03:38

4 because an actual batch had out-of-specification 03:38

5 blend uniformity samples? 03:39

6 A. The FDA cited? 03:39

7 Q. Yeah, which then went on uncorrected or 03:39

8 the tests weren't repeated? 03:39

9 A. It would -- there are references to 03:39

10 blend -- if I'm not mistaken there are references 03:39

11 in 483s and/or potentially EIRs with respect to 03:39

12 blend if I recall. I'd have to go back and dig 03:39

13 through and look at it specifically. 03:39

14 Q. Yeah, but do you know whether that had 03:39

15 to do with the way they investigated and the 03:39

16 number of samples -- and the number of samples 03:39

17 they took or whether it was actual blend 03:39

18 uniformity failures that were not addressed? 03:39

19 A. As I said, I would have to go back and 03:39

20 look specifically as what those discussions were. 03:39

21 It's been a while. 03:40

22 Q. Is it important to your opinions in this 03:40

23 case? 03:40

24 A. I think so, yes. 03:40

25 Q. Is there a difference between an actual 03:40

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1	blend uniformity failure that might require batch	03:40
2	rejection and some technical need to either	03:40
3	investigate differently or the way you did your	03:40
4	backup testing?	03:40
5	A. I don't understand that question.	03:40
6	Q. All right. It wasn't a very good	03:40
7	question. You'll find that late in the day with	03:40
8	this stuff, you can mess up the questions.	03:40
9	A. This is hard work.	03:40
10	Q. All right. So let's just assume that a	03:40
11	company takes ten core samples from various	03:40
12	sections of the blender for the blend uniformity	03:40
13	sampling; okay?	03:40
14	A. Yes.	03:40
15	Q. Now, let's assume that one of the ten is	03:40
16	out of specification.	03:40
17	A. Yes.	03:41
18	Q. Okay.	03:41
19	A. Uh-huh.	03:41
20	Q. A company is entitled to retest either a	03:41
21	portion of that sample or take a new sample from	03:41
22	that part of the blender, aren't they?	03:41
23	A. Retest, resample. You have to be very	03:41
24	careful on how you're defining those terms.	03:41
25	Q. Well, let's go back. Let's assume that	03:41

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1 the core sampling device, the sample thief. 03:41

2 A. Yes. 03:41

3 Q. Let's just assume for the sake of 03:41

4 argument -- 03:41

5 A. Uh-huh. 03:41

6 Q. -- that it is the length and diameter of 03:41

7 my pen -- 03:41

8 A. Okay. 03:41

9 Q. -- that I'm holding in front of the 03:41

10 camera; okay? 03:41

11 A. Uh-huh. 03:41

12 Q. So you put that in and you fill it with 03:41

13 blend. Actually, I think the sampling techniques 03:41

14 require a lot less than the length and diameter of 03:41

15 my pen. But let's assume you have enough to test, 03:42

16 okay, and you have some left over; all right? 03:42

17 A. Yes. 03:42

18 Q. Is there any FDA reg -- GMP or 03:42

19 otherwise -- that if the first test on the sample 03:42

20 is out of spec, it says that you have to reject 03:42

21 the batch and that you cannot test the remaining 03:42

22 sample in this sample field? 03:42

23 A. Well, there's a whole process that gets 03:42

24 to that, the resampling stage. If you have a 03:42

25 failure of an analysis in the laboratory, it 03:42

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1 requires a laboratory investigation to determine 03:42

2 whether that result is valid or not. 03:42

3 Q. Okay. But the question is, is there a 03:42

4 FDA reg that prevents you from testing more of the 03:42

5 sample that you took? 03:42

6 A. Not to my knowledge. 03:42

7 Q. Is there an FDA reg that prevents you 03:42

8 from resampling from that part of the blender and 03:43

9 then testing that material? 03:43

10 A. Not to my knowledge. 03:43

11 Q. Is there any FDA reg -- including GMP 03:43

12 regs -- that require companies to reject a batch 03:43

13 based on one out of say ten blend uniformity 03:43

14 tests? 03:43

15 A. Regulations? 03:43

16 Q. Yeah. 03:43

17 A. Not to my knowledge. 03:43

18 Q. So if we were to look at the Actavis 03:43

19 batch records and find that, for example, that on 03:43

20 initial testing, one sample was out of spec, and 03:43

21 the company did an investigation and retested and 03:43

22 it was not out of spec on retesting, you're not 03:44

23 saying that Actavis had to reject that batch for 03:44

24 blend uniformity failure, are you? Just answer my 03:44

25 question. 03:44

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1 A. Yeah. Say it again, please. These are 03:44  
2 very difficult issues. 03:44

3 Q. Sure. 03:44

4 A. Very difficult issues and they happened 03:44  
5 frequently. 03:44

6 Q. All right. So if you go into the 03:44  
7 records -- 03:44

8 A. Yes. 03:44

9 Q. -- you've had, all this paper, and you 03:44  
10 find that there was a blend uniformity out of spec 03:44  
11 result -- 03:44

12 A. Yes. 03:44

13 Q. -- for one out of ten samples for a 03:44  
14 particular batch; okay? 03:44

15 A. Uh-huh. 03:44

16 Q. Are you with me so far? 03:44

17 A. I am. 03:44

18 Q. And they retested it and it was within 03:44  
19 the specs and hence passed blend uniformity and 03:44  
20 was sent on for packaging, is it your opinion that 03:44  
21 that one out of spec result would have -- would 03:44  
22 have required rejection of the batch? 03:45

23 A. Perhaps. If you have a failure like 03:45  
24 this and you can't find a root cause for it and 03:45  
25 your investigation doesn't lead to anything, then 03:45

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1 there are some very serious discussions that need 03:45  
2 to be made with respect to the disposition of that 03:45  
3 batch. 03:45

4 Q. All right. But that doesn't 03:45  
5 automatically require a batch -- 03:45

6 A. Automatically -- 03:45

7 Q. -- rejection. 03:45

8 A. Automatically, knee jerk, no. 03:45

9 Q. You're supposed to -- the regs require 03:45  
10 that you do an investigation; correct? 03:45

11 A. Specifically I'd have to go back and 03:45  
12 look at the GMPs to see where they say -- excuse 03:45  
13 me -- say exactly that you must reject. It is 03:45  
14 expected in the industry that manufacturing 03:45  
15 investigations are investigated very thoroughly to 03:45  
16 determine a root cause. 03:45

17 Q. Okay. And it could be a manufacturing 03:45  
18 investigation or a lab investigation under these 03:46  
19 circumstances we're talking about with blend 03:46  
20 uniformity, couldn't it? 03:46

21 A. Yes, the lab in most cases is involved 03:46  
22 even if it is a manufacturing investigation 03:46  
23 because the laboratory people have a tendency to 03:46  
24 be some of the more technically trained folks on 03:46  
25 the staff and they usually are cross-functional 03:46

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1 teams when these types of issues come up. So you 03:46  
2 can solve the problem with the best information we 03:46  
3 have. 03:46

4 Q. So if there is a circumstance in the 03:46  
5 documents where this has occurred, FDA could go 03:46  
6 back and say we don't like the way you conducted 03:46  
7 the investigation and write up an observation and 03:46  
8 a 483 just about the way the investigation was 03:46  
9 done; correct? 03:46

10 A. That is correct. 03:46

11 Q. But not necessarily go the next step and 03:46  
12 say you should have rejected the batch. 03:46

13 A. It could; it could not. 03:47

14 Q. Right. 03:47

15 A. Uh-huh. 03:47

16 Q. But it doesn't follow as night does day 03:47  
17 that they would say you have to reject the batch. 03:47

18 A. Not to sound redundant, these are very 03:47  
19 complex issues and each one is separate and 03:47  
20 unique. 03:47

21 Q. And each one needs to be studied in this 03:47  
22 much detail; correct? 03:47

23 A. Absolutely. 03:47

24 Q. Now sitting here off the top of your 03:47  
25 head, without having to dive into these boxes, do 03:47

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1 you know exactly what the blend uniformity issues 03:47

2 were that FDA addressed in 483s regarding Digitek? 03:47

3 A. Without going back and diving into my 03:47

4 boxes, I can't tell you exactly what happened. 03:47

5 Q. Do you know off of top of your head 03:47

6 whether FDA ever cited, warned, sanctioned Actavis 03:47

7 for passing a batch at the blend uniformity stage 03:47

8 that FDA says should have been rejected? 03:47

9 A. There were discussions, if I recall, in 03:48

10 EIRs and 483s with respect to blend uniformity. 03:48

11 Q. That wasn't my question. 03:48

12 A. Okay. What was your question? 03:48

13 MR. MORIARTY: Read it back, Phil, 03:48

14 please. 03:48

15 (Whereupon, the testimony was read 03:48

16 back by the court reporter, as recorded above) 03:48

17 THE WITNESS: I can't off top of my head 03:48

18 answer that question. 03:48

19 BY MR. MORIARTY: 03:48

20 Q. If a pharmaceutical -- let me withdraw 03:48

21 that because I talked with you about that before. 03:49

22 Have you been shown any information whatsoever 03:49

23 to indicate that there was an outbreak of Digoxin 03:49

24 toxicity in 2006, 2007, or 2008 at any hospital, 03:49

25 nursing home, clinic, or outpatient facility in 03:49



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1 the United States? 03:49

2 A. When you say "outbreak" you mean? 03:49

3 Q. Up-tick, increase. 03:49

4 A. I know there's a document in here that 03:49

5 looks at adverse events and the numbers of them, 03:49

6 but that's all -- I would have to look at that and 03:49

7 speak to it. 03:49

8 Q. And you're not a pharmacovigilance 03:49

9 expert? 03:49

10 A. I am not. 03:49

11 Q. And do you know even know whether 03:49

12 adverse event reporting is considered by FDA to be 03:49

13 a causal connection? 03:49

14 A. Causal connection? 03:50

15 Q. Whether adverse event reporting is 03:50

16 necessarily caused by adulterated or out of spec 03:50

17 product? 03:50

18 A. It can be a flag, obviously. 03:50

19 Q. I understand that. 03:50

20 A. Yeah. 03:50

21 Q. For them to look that? 03:50

22 A. Yes. 03:50

23 Q. But if it did, it's not somebody makes 03:50

24 an adverse event report and you automatically 03:50

25 conclude that you have a problem with your 03:50

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1 manufacturing; right? Am I right about that? 03:50

2 A. Say that again, please. And it's late 03:50

3 in the day for me, too, so... 03:50

4 Q. Okay. Let's take a step back. These 03:50

5 lawyers hired a pharmacovigilance expert. 03:50

6 A. Okay. 03:50

7 Q. From Philadelphia, Karen Frank. 03:50

8 A. Okay. 03:50

9 Q. Would you defer to her on these 03:50  
10 pharmacovigilance issues? 03:50

11 A. Yes. 03:50

12 Q. So, what I was trying to -- oh, never 03:51  
13 mind. Other than what you said, about AERs, which 03:51  
14 you would defer to somebody else, you haven't seen 03:51  
15 evidence in medical literature or scientific 03:51  
16 publications that there was some increase in 03:51  
17 Digoxin toxicity in two or three years before this 03:51  
18 recall, have you? 03:51

19 A. I have not specifically gone out and 03:51  
20 looked for that in the literature. 03:51

21 Q. Have you talked to any cardiologists 03:51  
22 about this case, informally or otherwise? 03:51

23 A. In doctor-client privilege, I had 03:51  
24 discussion. 03:51

25 MR. KERENSKY: That's interesting, isn't 03:51

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1	it?	03:51
2	MR. MORIARTY: Yeah, this will be fun.	03:51
3	BY MR. MORIARTY:	03:51
4	Q. Do you take Digoxin?	03:51
5	A. I do not.	03:51
6	Q. And presumably you were not consulting a	03:51
7	doctor about a prescription for yourself --	03:51
8	A. No.	03:51
9	Q. -- when you were talking about Digoxin;	03:51
10	correct?	03:51
11	A. That's correct.	03:51
12	Q. And was the party to this conversation	03:52
13	your primary care physician?	03:52
14	A. Yes.	03:52
15	Q. Is he or she a cardiologist?	03:52
16	A. Yes.	03:52
17	Q. Okay. But the discussion had to do with	03:52
18	Digitek or Digoxin?	03:52
19	A. Where do we really fall on this? I'm	03:52
20	not really comfortable talking about what I talked	03:52
21	about with my doctor regarding this.	03:52
22	Q. Well, if you were talking about your own	03:52
23	medical care, then it's privileged and I'm going	03:52
24	somewhere else. If you were talking hey, buddy,	03:52
25	I'm consulting on this Digitek litigation. What	03:52

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1 do you know about it, what do you think about it, 03:52

2 that's not privileged because you weren't talking 03:52

3 to him about your own medical -- 03:52

4 A. I was not specifically asking him about 03:52

5 that. 03:52

6 MR. KERENSKY: Yeah, we don't 03:52

7 necessarily -- I don't necessary agree with 03:52

8 your characterization of where the line is on 03:53

9 what's privileged. And so there's an argument 03:53

10 just like he made and I made that the line is 03:53

11 here. There's an argument that everything you 03:53

12 talk to your doctor about in your doctor's 03:53

13 office is privileged; okay? I'm sure that's 03:53

14 what the doctor would say under HIPAA. 03:53

15 So it's your call whether or not you want 03:53

16 to share this with him. 03:53

17 THE WITNESS: I prefer not to talk about 03:53

18 it. 03:53

19 MR. KERENSKY: And if you guys want to 03:53

20 press it, just take it up with the Judge; 03:53

21 okay. 03:53

22 BY MR. MORIARTY: 03:53

23 Q. Did you show this doctor any documents 03:53

24 from the Digitek litigation? 03:53

25 A. I didn't think we were going to talk 03:53

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1 about this anymore. 03:53

2 Q. That's a different question. 03:53

3 A. No. 03:53

4 Q. Dr. Bliesner, you are aware that Digitek 03:54

5 has a theoretical batch yield, are you not? 03:54

6 A. Yes. 03:54

7 Q. So if you put the ingredients in 03:54

8 appropriately, if you're making .125 Digitek, you 03:54

9 should get 4.8 million Digitek tablets or 03:54

10 thereabouts; right? 03:54

11 A. Say that again. 03:54

12 Q. If you put the appropriate ingredients 03:54

13 into according to the formula, you should get 4.8 03:54

14 million tablets before waste, sampling, retained 03:54

15 samples, things of nature? 03:54

16 A. Without having gone back to look at it, 03:54

17 I'll trust you have the number and that's 03:54

18 accurate. 03:54

19 Q. Is there always at least some loss or 03:54

20 waste in the manufacturing process? 03:54

21 A. Invariably, yes. 03:55

22 Q. If a company consistently made 03:55

23 double-sized tablets, would the actual batch 03:55

24 production outcomes come close to the theoretical 03:55

25 yield numbers? 03:55

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1 A. I'm sorry. Say that again. 03:55

2 Q. If the company consistently made 03:55

3 double-sized the tablets -- 03:55

4 A. Uh-huh 03:55

5 Q. -- would the actual batch production 03:55

6 numbers come close to the theoretical yield 03:55

7 numbers? 03:55

8 A. I don't know. I would have to think 03:55

9 about that a little more. I don't think there's a 03:55

10 one-to-one correlation between theoretical yield 03:55

11 and this potential double-thick tablet. I 03:55

12 don't -- I would not speak definitively on that. 03:55

13 I have to really think about it. 03:55

14 Q. Well, if you made an entire batch 03:55

15 somehow of double-thick tablets -- 03:55

16 A. Uh-huh. 03:55

17 Q. -- are you going to get 4.8 million? 03:55

18 A. An entire batch? 03:55

19 Q. Yes, sir. 03:56

20 A. I would say that's probably not going to 03:56

21 get 4.8 million. 03:56

22 Q. If you made one quarter of the tablets 03:56

23 double thick, you wouldn't get close to 4.8 03:56

24 million either, would you? 03:56

25 A. No, I think you have to be very careful 03:56

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1 in trying to make those kinds of assessments 03:56  
2 because we don't know double-thick tablet again 03:56  
3 was ever testified. So we don't know what the 03:56  
4 weight is, we don't know what the total 03:56  
5 excipients, we don't know what the active is. We 03:56  
6 have no idea of being able to just off the top of 03:56  
7 your head, back of envelope calculation say how 03:56  
8 much it would be up short. I just don't think 03:56  
9 it's possible. 03:56

10 Q. Did you ever see any evidence in any 03:56  
11 company documents to indicate that there was some 03:56  
12 adverse trend in Digitek yield production? 03:56

13 A. If I recall, early on there was some 03:57  
14 discussions -- and it may have been with the 03:57  
15 FDA -- with respect to yield difficulties. 03:57

16 Q. What years are you talking about? 03:57

17 A. I don't know. Again, I'd have to go 03:57  
18 back and dig through the documents and look at 03:57  
19 them. 03:57

20 Q. Did any of that occur in 2005, 6, 7 or 03:57  
21 8? 03:57

22 A. I can't tell that you without going back 03:57  
23 and looking through them. 03:57

24 Q. Why, in general, do you think some 03:57  
25 problem that occurred in 1995, for example, is 03:57

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1 evidence that defective Digitek got into the hands 03:57  
2 of consumers in 2007 or 2008? 03:57

3 A. It's actually fairly straightforward. 03:57  
4 As I said in the report, primary difficulties in 03:57  
5 situations like this, in my experience and my 03:57  
6 opinion is lack of leadership. It's the number 03:57  
7 one. The people who were running the company back 03:58  
8 then when they had problems with first consent 03:58  
9 decree up until just before the second consent 03:58  
10 decree are same people who are running people the 03:58  
11 same people on regulatory force, the same people 03:58  
12 in quality, the same people that caused all the 03:58  
13 initial problems were still there. 03:58

14 Q. Is that some scientific theory? 03:58

15 A. It's a -- it's a statement of fact. 03:58

16 Q. So, in other words essentially what 03:58  
17 you're saying is because they were sloppy in '95 03:58  
18 means they must have been sloppy in '06 and '07? 03:58

19 A. I think the information that I've 03:58  
20 reviewed pretty consistently shows they got out 03:58  
21 from underneath the consent decree, they became 03:58  
22 recidivistic, and they moved right back into 03:58  
23 another situation with many of these same 03:58  
24 problems. That reflects on leadership. 03:58

25 Q. But not one thing that you just told me 03:58



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1 is scientific evidence of defective tablets 03:58

2 getting into the hands of consumers. Are you 03:59

3 talking about FDA documents? 03:59

4 A. It's a failure of quality which impacts 03:59

5 the quality of the product going out the door. 03:59

6 Q. Well, if the quality was so bad from '95 03:59

7 through 2008 -- let's just pick that period of 03:59

8 time, those 13 years -- shouldn't there be some 03:59

9 evidence of defective Digitek getting into the 03:59

10 hands of consumers? 03:59

11 A. There are evidence. The pharmacy 03:59

12 individuals. 03:59

13 Q. One tablet out of a billion. Got 03:59

14 anything else? 03:59

15 A. As far as scientific data specifically 03:59

16 showing that it was in the hands of the 03:59

17 individual? 03:59

18 Q. Yes. 03:59

19 A. There was nothing in the record. 03:59

20 However, you know, you have a billion tablets 03:59

21 let's say. It's the number everybody's throwing 03:59

22 around. Start doing the math, say it's .00001 03:59

23 percent, you know, how many tablets is that? 03:59

24 There's a lot of tablets in the market and you may 03:59

25 never seen it. They could hurt the people. 04:00

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1 Q. You may never see it; right? 04:00

2 A. That exists. 04:00

3 Q. Okay. So the one tablet that was found 04:00

4 in 2003 or 4 was found by a pharmacist, wasn't it? 04:00

5 A. I believe that's what we said earlier. 04:00

6 Q. Have you ever worked in a pharmacy? 04:00

7 A. I have not. 04:00

8 Q. Do you have any expertise in pharmacy? 04:00

9 A. A pharmacist? No, sir. 04:00

10 Q. Well, if the one tablet we know about in 04:00

11 2004 could be detected by a pharmacist, isn't it 04:00

12 reasonable to conclude that other extra-thick 04:00

13 tablets, if they existed, would be detected by 04:00

14 pharmacists? 04:00

15 A. Could be. 04:00

16 Q. But that is the only one you know 04:00

17 about. 04:00

18 A. Those two specific instances and the 04:00

19 documents I've reviewed. 04:00

20 Q. Let's talk about sampling rates. Are 04:01

21 you an expert in the design and implementation of 04:01

22 sampling plans for in-process pharmaceutical 04:01

23 testing? 04:01

24 A. I am not. 04:01

25 Q. Do you at least know that in-process 04:01

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1 sampling plans are FDA approved? 04:01

2 A. In the application? Is that what you're 04:01

3 asking? 04:01

4 Q. Initially in the AMDA; correct. 04:01

5 A. I'm not sure whether that specific 04:02

6 sample plan exists in the AMDA. I would have to 04:02

7 take a look. I know procedures, internal guidance 04:02

8 and SOPs companies have with respect to sampling, 04:02

9 and they are pretty unique. 04:02

10 Q. Are you aware of any 483 or warning 04:02

11 letter comment at any point from 2005 to 2008, 04:02

12 which observed problems with Digitek in-process 04:02

13 sampling, meaning weight, thickness? 04:02

14 A. Specific physical testing? 04:02

15 Q. Hardness. 04:02

16 A. I have not seen any that I recall. 04:02

17 Q. And I assume that this sort of 04:02

18 in-process testing in general is supposed to tell 04:02

19 you something about the consistency of the tablets 04:02

20 that are coming off the presses; is that right? 04:02

21 A. At various stages within the process. 04:03

22 It's not like you just grab a hold and spot. 04:03

23 In-process testing involves -- as you said, you've 04:03

24 already said -- blend uniformity at certain steps 04:03

25 along the way. 04:03

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1 Q. Well, right now I'm just talking about 04:03  
2 the thickness, hardness, the color, weight. 04:03

3 A. That's kind of -- as far as in-process 04:03  
4 goes? 04:03

5 Q. Yeah. 04:03

6 A. I'm not -- okay, I don't recall what 04:03  
7 their in-process tests were for this particular 04:03  
8 product. 04:03

9 Q. But you've not seen any FDA citations or 04:03  
10 warning implicating those processes? 04:03

11 A. Not that I recall. 04:03

12 Q. But I am correct that what you do in 04:03  
13 there when QA comes in and the actual press 04:03  
14 operator is checking, is to see at least visually 04:03  
15 and by measurement whether the tablets are 04:03  
16 consistent in size, weight, hardness, things of 04:03  
17 that nature; correct? 04:03

18 A. It's a limited testing in process to see 04:03  
19 where you are, how it's progressing. 04:04

20 Q. But that's what it's designed to tell 04:04  
21 you, limited as it may be? 04:04

22 A. Yes. 04:04

23 Q. So let's talk about finished product 04:04  
24 testing, which is within your bailiwick. Did the 04:04  
25 AMDA have description of the methods that would be 04:04

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1 used to assay content uniformity and dissolution 04:04

2 tests Digitek at the finished product stage? 04:04

3 A. Not specifically looking at the ANDA. I 04:04

4 remember -- I'm pretty sure the methods would be 04:04

5 in there. They should be. 04:04

6 Q. Are they also -- 04:05

7 A. I need to interject here that I'm not 04:05

8 sure that I had an opportunity to review all of 04:05

9 the sections of the ANDA when they were up on the 04:05

10 website for me. So I got to be careful here. I'm 04:05

11 not sure if I had the whole package 04:05

12 Q. Have you looked at the method operating 04:05

13 instructions or anything else regarding the 04:05

14 testing methods? 04:05

15 A. I have looked at some methods. I would 04:05

16 have to go back and look and see what specific 04:05

17 methods there were. 04:05

18 Q. I didn't see any criticism in your 04:05

19 report of Actavis's method for finished process 04:05

20 testing Digitek. Am I correct about that? 04:05

21 A. There is nothing in the report. 04:05

22 However, I was not pointed specifically to look at 04:05

23 methods in particular. I did not do a wholesale, 04:05

24 soup to nuts -- as I normally do -- review of the 04:05

25 laboratory control system. 04:05

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1 Q. When you say as you normally do in a lab 04:05  
2 control system, you mean for a consulting 04:05  
3 non-litigation project; right? 04:06

4 A. Yes. 04:06

5 Q. Well, certainly if the Plaintiffs' 04:06  
6 lawyers were concerned about the finished product 04:06  
7 methods, they would have probably pointed you in 04:06  
8 that direction; correct? 04:06

9 A. I wouldn't make that conclusion. We ran 04:06  
10 out of time as much as anything else. 04:06

11 Q. And excuse me if I asked you this 04:06  
12 before, but you have not seen in any 483 or 04:06  
13 warning letter any sort of statement by FDA that 04:06  
14 Actavis's finished product testing of Digitek was 04:06  
15 in some way deficient; correct? 04:06

16 A. No, we did not talk about that. And I 04:06  
17 vaguely recall that there are discussions with 04:06  
18 respect to analytical methods not being sufficient 04:06  
19 for their intended use and/or validated in some of 04:06  
20 these documents that the FDA has generated. I 04:06  
21 have to go back and look at them. 04:07

22 Q. For Digitek? 04:07

23 A. I can't say for certain, but I know that 04:07  
24 there are discussions through 483s and warnings 04:07  
25 letters with respect to the laboratory records and 04:07

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1 methods. 04:07

2 Q. Did FDA ever say that there was a batch 04:07

3 that had out-of-spec results that should have been 04:07

4 rejected because the methods or even the 04:07

5 investigations were inadequate? 04:07

6 A. Methods? 04:07

7 Q. Or investigations? 04:07

8 A. Or investigations. Again, I'd have to 04:07

9 go back and look at it because there are 04:07

10 discussions with respect to methods, methods 04:07

11 validation and testing that come up throughout 04:07

12 these FDA documents. 04:07

13 Q. But my question is very specific. 04:07

14 A. Okay. 04:08

15 Q. Do you remember any statements in any 04:08

16 FDA documents to the effect that Digitek batches 04:08

17 should have been rejected because analytical 04:08

18 methods were inadequate or investigations were 04:08

19 inadequate? 04:08

20 A. I can't say that off the top of my 04:08

21 head. I really can't. Analytical methodology is 04:08

22 invariably one of the observations the FDA makes 04:08

23 for companies in trouble. 04:08

24 Q. Let's go to page 7 of your report. 04:08

25 MR. KERENSKY: Can we take a stretch 04:09

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1	break after you finish this thing, this little	04:09
2	subject?	04:10
3	MR. MORIARTY: How long on the tape?	04:10
4	THE VIDEOGRAPHER: 25 minutes.	04:10
5	MR. MORIARTY: Yeah.	04:10
6	BY MR. MORIARTY:	04:10
7	Q. Okay. Page 7.	04:10
8	A. Yes.	04:10
9	Q. It says product recalls.	04:10
10	A. Yes.	04:10
11	Q. The first one is in 1990. Was that	04:10
12	Digitek?	04:10
13	A. I don't know.	04:10
14	Q. What would you have to look at to figure	04:10
15	it out?	04:10
16	A. It was just a -- if I recall, it was a	04:10
17	business summary that was presented by one of the	04:10
18	CEOs and it just said there was a product recall.	04:10
19	If I -- I'm pulling this off my memory, which I	04:10
20	hesitate to do that.	04:10
21	Q. In 1995, Class III?	04:10
22	A. Uh-huh.	04:10
23	Q. That's not recalled at the consumer	04:10
24	level; correct?	04:10
25	A. Uh-huh.	04:10



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1	Q.	Is that right?	04:10
2	A.	That's correct.	04:10
3	Q.	Because of incorrect package insert.	04:10
4		Which is, in your words, a failure of packaging	04:11
5		and labeling portions of the cGMPs; correct?	04:11
6	A.	Correct.	04:11
7	Q.	Was it Digitek?	04:11
8	A.	I'd have to look. That may be one of	04:11
9		those things as well that was just stated as.	04:11
10	Q.	And certainly FDA or Amide at the time	04:11
11		didn't consider this as a patient safety issue	04:11
12		because it was a Class III recall; correct?	04:11
13	A.	Correct. An immediate threat.	04:11
14	Q.	And the 2008 August total product	04:11
15		recall, which is the last one that you list --	04:11
16	A.	Yes.	04:11
17	Q.	-- that was a Class III recall, wasn't	04:11
18		it?	04:11
19	A.	I don't recall.	04:11
20	Q.	Well, that's important to know, isn't	04:11
21		it?	04:11
22	A.	Let's take a look.	04:11
23		MR. MORIARTY: Let me make sure we're on	04:12
24		the same page.	04:12
25		THE WITNESS: Okay.	04:12

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1	BY MR. MORIARTY:	04:12
2	Q. Was the 2008 August recall to the	04:12
3	consumer level?	04:12
4	A. What page were we on again back in the	04:12
5	document?	04:12
6	Q. Seven.	04:12
7	A. Seven?	04:12
8	Q. But you don't have a reference?	04:12
9	A. Seven, the August recall?	04:12
10	Q. Yeah, I guess you would be looking at	04:12
11	A49, A55, 63. That's what your table says	04:12
12	A. 25 April, 2008?	04:13
13	Q. No, sir. August 2008. It would be your	04:13
14	reference A63.	04:13
15	A. 63.	04:13
16	Q. And on page 61 of your report you say	04:13
17	that it was recalled at the retail level.	04:13
18	A. Where in the report?	04:13
19	Q. Page 61.	04:13
20	A. Yeah. 61, reference A63?	04:13
21	Q. Yes, sir.	04:14
22	A. Recall from press release, FDA website	04:14
23	"Actavis auto announces voluntary recall at retail	04:14
24	level of all drugs manufactured." Then that's	04:14
25	what that was.	04:14

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1 Q. All right. So even though FDA may have 04:14  
2 been concerned about good manufacturing practice 04:14  
3 violations in 2008 or 2007, there was not a recall 04:14  
4 of these other products to the consumer level; 04:14  
5 correct? 04:14

6 A. According to that. 04:14

7 MR. MORIARTY: Okay. You want to take a 04:14  
8 stretch break? Let's go off the record for -- 04:14

9 MR. KERENSKY: Thank you for remembering. 04:15

10 MR. MORIARTY: For five minutes. 04:15

11 THE VIDEOGRAPHER: The time is 4:17 p.m. 04:15  
12 We're going off the record. 04:15

13 THE VIDEOGRAPHER: The time is now 04:25  
14 4:28 p.m. We are back on the record. 04:25

15 (Whereupon, Exhibit 106 was marked 04:26  
16 for identification) 04:26

17 BY MR. MORIARTY: 04:26

18 Q. Okay. I'm going to show you what has 04:26  
19 been marked as Exhibit 106; okay? This is a 04:26  
20 notice of your deposition for today; all right? 04:26

21 A. Okay. 04:26

22 Q. Have you seen that before? 04:26

23 A. I have. 04:26

24 Q. All right. And it tells you to bring a 04:26  
25 lot of stuff; right? 04:26

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1 A. Yes. 04:26

2 Q. So when this is going to be restarted on 04:26

3 the 18th, there will be a new notice that goes 04:26

4 out. You will have to bring your stuff and 04:26

5 somehow the lawyers will figure out a way to get 04:26

6 this hard drive duplicated so we can find these 04:26

7 other things; okay? 04:26

8 A. Okay. 04:26

9 Q. So it's possible you'll have to be in 04:26

10 communication with people between now and then -- 04:26

11 A. Yes. 04:26

12 Q. -- to facilitate that; all right. 04:26

13 Okay. Fair enough. 04:27

14 MR. ANDERTON: We should plan to start 04:27

15 perhaps as early at 8 o'clock on the 18th? 04:27

16 THE WITNESS: That's fine. 04:27

17 BY MR. MORIARTY: 04:27

18 Q. Let's go to page 8 of your report. Do 04:27

19 you see in the middle of the page where you have 04:27

20 the three bullet points? 04:27

21 A. Yes. 04:27

22 Q. Does it gives the three addresses? 04:27

23 A. Yes. 04:27

24 Q. All right. Do you know that Taft Road 04:27

25 was only a packaging facility for Digitek? 04:27

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1 A. I knew that it was in limited 04:27  
2 operations. Specifically packaging, I don't know 04:27  
3 if I could -- I could say that definitively 04:27  
4 without going back and looking at the EIR. 04:27

5 Q. Do you remember anything in a 483 or a 04:27  
6 warning letter or an EIR to the effect that there 04:28  
7 was a problem in any facility of Taft Road that 04:28  
8 affected the potency of Digitek that made it to 04:28  
9 consumers? 04:28

10 A. I can't say without going back. It gets 04:28  
11 pretty complex on what the facilities are and how 04:28  
12 they are, what's going on at them. It's kind of a 04:28  
13 mess just breaking out what the three were. So 04:28  
14 I -- I can't definitively answer that, sorry. 04:28

15 Q. And do you know what was going on at 990 04:28  
16 Riverview Drive? 04:28

17 A. Again, it's the same thing. Very 04:28  
18 confusing reviewing documents what specific 04:28  
19 operations were going on at these individual 04:28  
20 facilities. 04:28

21 Q. Well -- 04:28

22 A. And how they impacted or didn't. 04:28

23 Q. Hypothetically I want to you assume that 04:28  
24 all that was going on at Riverview was -- from a 04:29  
25 production standpoint was the attempt to validate, 04:29

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1 process validate a new location with different 04:29

2 equipment to manufacture Digitek; okay? 04:29

3 A. Theoretically; okay. 04:29

4 Q. No. 04:29

5 A. That's what you're saying. 04:29

6 Q. No, I'm asking you to assume that. 04:29

7 A. Hypothetically. 04:29

8 Q. And that no product from Riverview was 04:29

9 ever released to market at all; okay. 04:29

10 A. If that's what you say hypothetically, 04:29

11 yeah. 04:29

12 Q. So if, for example, they had a problem 04:29

13 some day with an oil leak on a tableting machine 04:29

14 and tablets got oily but were, you know, rejected 04:29

15 because they were not going to market anyway, that 04:29

16 wouldn't affect the potency of Digitek that 04:29

17 actually was made at Little Falls and shipped to 04:29

18 consumers, would it? 04:30

19 A. What facility are we talking about? 04:30

20 Q. Riverview. 04:30

21 A. Riverview. Okay. And you're saying 04:30

22 that hypothetically if there was problem at 04:30

23 Riverview where they're only doing process 04:30

24 validation; is that correct? 04:30

25 Q. Yeah. 04:30

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1 A. That that action would not influence 04:30

2 what was going on at the Little Falls facility. 04:30

3 Is that what you're saying? 04:30

4 Q. Yes. 04:30

5 A. Yes, hypothetically, yes. 04:30

6 Q. Okay. Well, do you have any evidence 04:30

7 that any Digitek that was made at Riverview was 04:30

8 released to consumers? 04:30

9 A. Other than going back and digging 04:30

10 through documents, I can't say that explicitly. 04:30

11 I -- it's just -- it's too much to go back and 04:30

12 piece together. 04:30

13 Q. Okay. Miss Donahue represents Mylan. 04:31

14 Do you know who Mylan is? 04:31

15 A. I do. 04:31

16 Q. Do you know that they were only a 04:31

17 distributor not a manufacturer of Digitek? 04:31

18 A. Is that a totally accurate statement 04:31

19 because I don't know if I understand the 04:31

20 relationship, UDL, Bertek, how they fall into 04:31

21 that. 04:31

22 Q. Do you know whether Digitek was ever 04:31

23 manufactured by anyone other than Amide or 04:31

24 Actavis? 04:31

25 A. I don't know that definitively because I 04:31

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1 know there was discussion that Mylan was going to 04:31

2 take it over via UDL or Bertek, so I don't know. 04:31

3 Q. Well, have you seen any documents to 04:31

4 indicate that Mylan or UDL ever manufactured 04:31

5 tablets of Digitek? 04:32

6 A. I don't believe that they did. 04:32

7 MR. MORIARTY: Okay. The bottom line is 04:32

8 she has a couple of questions that she wants 04:32

9 to get out of the way during session one. So 04:32

10 I'm going to let her ask those questions and 04:32

11 then if there's time left on my tape, I'll get 04:32

12 back to you; okay? 04:32

13 THE WITNESS: Okay. 04:32

14 DIRECT EXAMINATION 04:32

15 BY MS. DONAHUE: 04:32

16 Q. Good afternoon, Dr. Bliesner. 04:32

17 A. Hello. 04:32

18 Q. I have reviewed your -- first, let me 04:32

19 start by asking you this. 04:32

20 A. Yes. 04:32

21 Q. You are not an expert in pharmaceutical 04:32

22 distribution, are you? 04:33

23 A. Distribution, no. 04:33

24 Q. And you're not an expert on the industry 04:33

25 practices related to pharmaceutical distribution? 04:33



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1 A. Distribution, no. 04:33

2 Q. You're not expert on the FDA regulations 04:33

3 applicable to pharmaceutical distribution? 04:33

4 A. I have not -- I mean don't even know 04:33

5 what specifically the regulations would relate to 04:33

6 distribution, so, no. 04:33

7 Q. So you're not expert? 04:33

8 A. No. 04:33

9 Q. And you've never published any articles, 04:33

10 textbooks, treatises on pharmaceutical 04:33

11 distribution practices? 04:33

12 A. I have not. 04:33

13 Q. Now, I reviewed your 21-plus attachment 04:33

14 page report before coming here today. 04:33

15 A. Yes. 04:33

16 Q. And the purpose of that report is set 04:33

17 forth on page 1 of your report; correct? 04:33

18 A. Correct. 04:33

19 Q. And can you read that purpose out loud, 04:33

20 please, for the record? 04:34

21 A. Sure. Purpose: "This report is a 04:34

22 thorough, detailed, independent review of the 04:34

23 facts related to Digitek product litigation. In 04:34

24 particular, this review is specifically conducted 04:34

25 to determine if Amide Pharmaceutical, Inc. which 04:34

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1 later became Actavis Totowa, LLC and referred to 04:34  
2 as Amide/Actavis within this report, demonstrated 04:34  
3 a systematic failure to implement quality systems 04:34  
4 which in turn created a high likelihood that 04:34  
5 adulterated product made it to the marketplace." 04:34

6 Q. Thank you. And is that an accurate 04:34  
7 statement of the purpose of your report? 04:34

8 A. Yes. 04:34

9 Q. And I think you told me -- you told us 04:34  
10 earlier in response to Mr. Moriarty's questions, 04:34  
11 that -- let's see. When you first were contacted 04:34  
12 by Plaintiffs' counsel in these cases, your task 04:34  
13 or the guidance they gave you was to evaluate the 04:34  
14 status of Actavis's or Amide's compliance with 04:34  
15 GMPs; is that correct? 04:34

16 A. Yes, that's correct. 04:34

17 Q. If we turn to page -- the bottom of page 04:35  
18 20 of your report under the heading root causes 04:35  
19 for Amide Pharmaceutical and Actavis's failure to 04:35  
20 comply with GMPs which led to release of 04:35  
21 adulterated product to market. 04:35

22 A. Yes. 04:35

23 Q. You see that there? 04:35

24 A. I do. 04:35

25 Q. And then you have list of the root 04:35

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1 causes; right? 04:35

2 A. Yes. 04:35

3 Q. And nowhere among the one, two, three, 04:35

4 four, five root causes that you've identified in 04:35

5 your report is there mention of any conduct on 04:35

6 behalf of -- or on the part of Mylan or UDL as a 04:35

7 root cause; is that correct? 04:35

8 A. Specifically, "yes, but." Mylan was 04:36

9 contracted to have amide then or Actavis 04:36

10 manufacture the tablets, and there was no quality 04:36

11 agreement that was in place that I saw in the 04:36

12 record. 04:36

13 So lack of quality assurance oversight 04:36

14 overlaps into that because the innovator, as I 04:36

15 understand, or the head of the contract -- Mylan 04:36

16 in this case as I understand as I read it -- is 04:36

17 responsible for the product as well and making 04:36

18 sure that their contractors, contract 04:36

19 manufacturers, whatever, follow the GMPs. 04:36

20 Q. Have you been asked in this case by 04:36

21 Plaintiffs' counsel to provide an opinion as to 04:36

22 Mylan's alleged liability? 04:36

23 A. Formally, prior to this? 04:36

24 Q. Yes. 04:36

25 A. Prior to this session? 04:37

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1 Q. Yes. 04:37

2 A. No. 04:37

3 Q. Prior to authoring your report, were you 04:37  
4 asked by Plaintiffs' counsel to render a report as 04:37  
5 to Mylan's liability in these cases? 04:37

6 A. I recall the discussion with the Miller 04:37  
7 law firm regarding Mylan and asked for guidance. 04:37  
8 This is from memory, so it's not written down. 04:37  
9 It's a bit vague. And they -- their guidance was, 04:37  
10 you know, however they fit into this, put it in 04:37  
11 your report as you see fit. 04:37

12 Q. And you saw fit not to mention Mylan 04:37  
13 specifically or any specific Mylan conduct in the 04:37  
14 report that you've stated was -- was written for 04:37  
15 the purpose of advising counsel as to what your 04:37  
16 opinions are in this case. 04:37

17 A. There are references in the attachment 04:37  
18 section to discussions with Mylan that talk about 04:38  
19 quality issues they were concerned with for some 04:38  
20 time. 04:38

21 Q. Okay. Can you please point to me -- 04:38

22 A. Sure. 04:38

23 Q. -- in your attachments every reference 04:38  
24 to Mylan. 04:38

25 A. Okay. 04:38

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1	MR. MORIARTY: I think this is going to	04:38
2	take a couple of minutes. You might want to	04:38
3	go off the video record.	04:38
4	THE VIDEOGRAPHER: The time is 4:41 p.m.	04:38
5	We're going off the record briefly.	04:38
6	(Short break)	04:39
7	THE VIDEOGRAPHER: The time is now	04:39
8	4:49 p.m. We are back on the record.	04:46
9	BY MS. DONAHUE:	04:46
10	Q. All right. Dr. Bliesner, off the record	04:46
11	you were reviewing your report --	04:46
12	A. Yes.	04:46
13	Q. -- in order to answer my question which	04:46
14	was where -- will you please point out every	04:46
15	reference in your report to a Mylan document.	04:46
16	A. Yes. The other question I have, are you	04:46
17	considering UDL Bertek to be part of the Mylan	04:47
18	umbrella?	04:47
19	Q. Sure.	04:47
20	A. Okay. Page 15, number 33.	04:47
21	Q. Uh-huh. Yes. Thank you. We have	04:47
22	number page 15, number 33?	04:47
23	A. Yes.	04:47
24	Q. Yes.	04:47
25	A. Page 18, number 46.	04:47

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1	Q.	Yes.	04:47
2	A.	And number 49. Page 19, number 54.	04:47
3	Q.	Any others?	04:47
4	A.	Yes. Page 41, number A24; page 43, A28;	04:47
5		page 46, A33; page 47, A36; page 54, A44; page 56	04:48
6		A 49; page 57 A52; page 58, A53.	04:49
7		There is a reference to Bertek UDL in A55 on	04:50
8		page 59, embedded in the press release, and on	04:50
9		page 60, A59. And I believe with that quick	04:50
10		review of the report, that should be most all of	04:50
11		them.	04:50
12	Q.	Thank you.	04:50
13	A.	Uh-huh.	04:50
14	Q.	Now each of those references that you've	04:50
15		just given us to Mylan documents, are just that;	04:50
16		correct? They are references to Mylan documents	04:50
17		and in some instances quotations from the	04:50
18		documents; is that correct?	04:50
19	A.	For e-mails, yes.	04:50
20	Q.	And nowhere in the course of those	04:50
21		references have you rendered an opinion in regard	04:50
22		to Mylan or UDL's conduct in distributing Digitek?	04:50
23	A.	In this report?	04:51
24	Q.	Yes.	04:51
25	A.	I have not written it in the report. I	04:51

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1 do have an opinion, but I have not written it in 04:51  
2 the report. 04:51

3 Q. Did you have an understanding as you 04:51  
4 came here today that your report was to contain 04:51  
5 the totality of your opinions that you intend to 04:51  
6 render at trial in this case? 04:51

7 A. With respect to the guidance that I got, 04:51  
8 thought and think and do believe that I put the 04:51  
9 information that was desired specifically related 04:51  
10 to Digitek, Actavis Totowa. That was my guidance. 04:51

11 MR. MORIARTY: You have 60 seconds. 04:51

12 BY MS. DONAHUE: 04:51

13 Q. As you sit here today, what is your 04:52  
14 opinion with regard to Mylan's conduct in the 04:52  
15 distributing Digitek in the case, Mylan and UDL? 04:52

16 A. Just based upon the documents that I 04:52  
17 reviewed and, again, not concentrating on Mylan's 04:52  
18 position in this thing, I found it odd and not 04:52  
19 customary that no quality agreement was in place. 04:52

20 Q. You would agree, would you not, that 04:52  
21 quality agreements are not required by the FDA 04:52  
22 regulations? 04:52

23 A. By regulations? Specifically in 21 CFR 04:52  
24 210 and 211, not to my knowledge is there a 04:52  
25 requirement for a quality agreement. It is 04:52

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1 standard industry practice. 04:52

2 Q. That's a relatively new standard 04:52

3 industry practice, would you agree with that? 04:52

4 A. Relatively new? I'm not sure how you 04:52

5 define relatively new. 04:52

6 Q. In your opinion, when did it become 04:53

7 standard industry practice? 04:53

8 A. Well, let's see. For the last -- at 04:53

9 least the last three to five years in my 04:53

10 consulting endeavors I've expected and seen 04:53

11 quality agreement with contractors. 04:53

12 Q. Do you understand that as you sit here 04:53

13 today, Dr. Bliesner, that Mylan or -- neither 04:53

14 Mylan or UDL was the innovator in regard to 04:53

15 Digitek? In other words, neither one of them held 04:53

16 the ANDA? 04:53

17 A. That is correct. I understand that. 04:53

18 MS. DONAHUE: Since we're almost out of 04:53

19 tape, I'm going to stop questioning now, but I 04:53

20 reserve the right to come back. 04:53

21 Oh, yeah. Before we go off the record, 04:53

22 let me finish my sentence. I reserve the 04:53

23 right to come back and continue my 04:53

24 questioning. And you've been, I think, taking 04:53

25 some notes during the deposition and we would 04:53



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1 like to get those marked as an exhibit, 04:54

2 please. 04:54

3 THE WITNESS: Okay. 04:54

4 MS. DONAHUE: Let's wait. Before we go 04:54

5 off the record, let's mark them. 04:54

6 MR. KERENSKY: You didn't write anything 04:54

7 down about Mr. Anderton's tie, did you? 04:54

8 THE WITNESS: No, it was noted though. 04:54

9 MR. KERENSKY: Okay. 04:54

10 MR. ANDERTON: I will accept the 04:54

11 compliment. 04:54

12 (Whereupon, Exhibit 109 was marked 04:54

13 for identification) 04:54

14 THE VIDEOGRAPHER: The time is now 04:54

15 4:57 p.m. We're going off the record. 04:54

16

17 (THEREUPON, the taking of the deposition  
18 was concluded at 4:57 p.m.)

19

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CERTIFICATE OF OATH

STATE OF FLORIDA

COUNTY OF HILLSBOROUGH

I, the undersigned authority,  
certify that David Bliesner, Ph.D., personally  
appeared before me and was duly sworn by me.

WITNESS my hand and official  
seal, this 3rd day of February, 2011.

---

PHILIP RYAN, RPR  
NOTARY PUBLIC - STATE OF FLORIDA  
COMMISSION # DD 988415  
MY COMMISSION EXPIRES: JUNE 28, 2014

1 CERTIFICATE OF REPORTER

2 STATE OF FLORIDA

3 COUNTY OF HILLSBOROUGH

4 I, PHILIP RYAN, RPR, certify that I  
5 was authorized to and did stenographically  
6 report the foregoing deposition; and that the  
7 foregoing transcript is a true record of the  
8 testimony given by the witness.

9 I further certify that I am not a  
10 relative, employee, attorney, or counsel of any  
11 of the parties, nor am I a relative or employee  
12 of any of the parties' attorneys or counsel  
13 connected with the action, nor am I financially  
14 interested in the action.

15

16 DATED this 3rd day of February,  
17 2011.

18

19

20

21

22 \_\_\_\_\_  
PHILIP RYAN, RPR

23

24

25

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IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION

MDL NO: 1968

IN RE: DIGITEK PRODUCT LIABILITY  
LITIGATION,

\_\_\_\_\_ /

100 N. Tampa Street  
Suite 2900  
Tampa, FL 33602  
February 18, 2011  
at 8:15 a.m.

VIDEOTAPE DEPOSITION OF DAVID BLIESNER, Ph.D.

Taken on behalf of the Defendants before  
PHILIP RYAN, RPR, Court Reporter, Notary Public in  
and for the State of Florida at Large, pursuant to  
Defendant's Notice of Taking Deposition in the  
above cause.

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1 APPEARANCES:

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 Inc., Mylan Inc., Mylan Bertek  
 16 Pharmaceuticals, Inc., and UDL Labs

17 ALSO PRESENT:

Alan Pokotilow, videographer

18

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20 BY MR. ANDERTON

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1 THE VIDEOGRAPHER: We're on the 08:15  
2 record at 8:15 a.m. The date today is 08:15  
3 February 18th of 2011. This is the videotape 08:15  
4 deposition of Dr. David M. Bliesner in regard 08:15  
5 to the Digitek product liability litigation, 08:16  
6 civil action MDL 1968. 08:16

7 This videotape deposition is being held 08:16  
8 at 100 North Tampa, within suite 2900. The 08:16  
9 deposition was noticed by attorney Matt 08:16  
10 Moriarty, I believe. 08:16

11 MR. ANDERTON: Richard Dean, actually. 08:16

12 THE VIDEOGRAPHER: Okay. The 08:16  
13 videographer is Alan Pokotilow and the court 08:16  
14 reporter is Philip Ryan. At the time of 08:16  
15 transcript, the tape will be archived at 08:16  
16 Renillo Deposition and Discovery. 08:16

17 Counsel, please state your name and 08:16  
18 affiliation for the record, after which our 08:16  
19 court reporter will swear the witness and we 08:16  
20 can proceed. 08:16

21 MR. ANDERTON: Michael Anderton with 08:16  
22 Tucker Ellis & West on behalf of the Activis 08:16  
23 Defendants. 08:16

24 MS. DREWES: Sarah Drewes, with Shook, 08:16  
25 Hardy & Bacon on behalf of the Mylan 08:16

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1 Defendants. 08:16

2 MR. KERENSKY: Mike Kerensky for the 08:16

3 Plaintiff Mimi Vega. 08:16

4 MR. ANDERTON: And just so the record is 08:16

5 clear, Mr. Kerensky is participating by 08:17

6 telephone. 08:17

7 MR. KERENSKY: Correct. 08:17

8 The Deponent herein, 08:17

9 DAVID BLIESNER, Ph.D., 08:17

10 Being first duly sworn to tell the truth, the 08:17

11 whole truth, and nothing but the truth, was 08:17

12 examined and testified as follows: 08:17

13 DIRECT EXAMINATION 08:17

14 BY MR. ANDERTON: 08:17

15 Q. Good morning, Dr. Bliesner. 08:17

16 A. Good morning, sir. 08:17

17 Q. How are you? 08:17

18 A. Okay. 08:17

19 Q. Thanks for accommodating the early start 08:17

20 time. 08:17

21 A. Sure. 08:17

22 Q. I know it's an early day, but if we're 08:17

23 going to get everybody home to spend time with 08:17

24 their families this weekend, I thought 8 o'clock 08:17

25 was the best time to start. So thank you. 08:17



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1 A. You're welcome. 08:17

2 Q. Some ground rules. I know you -- we did 08:17

3 this about two or three weeks ago now, a little 08:17

4 more than three weeks ago so you're familiar with 08:17

5 the process, but I just want to repeat some ground 08:17

6 rules. And if you have any questions about them, 08:17

7 kind of let me know; okay? 08:17

8 A. Okay. 08:17

9 Q. As you know, I'm going to ask questions, 08:17

10 you're going to answer my questions. If you don't 08:17

11 understand a question, I would ask that you tell 08:17

12 me that and ask me to rephrase it or to state it 08:18

13 differently; is that fair? 08:18

14 A. That is fair. 08:18

15 Q. All right. And if I ask a question and 08:18

16 you answer it without asking me to rephrase or 08:18

17 restate it somehow, I will assume that you 08:18

18 understood it. 08:18

19 Is that all right? 08:18

20 A. Okay. 08:18

21 Q. You need to keep your voice up probably 08:18

22 just a little. I know you're mic'd and I know 08:18

23 from the last time that you're -- at times at 08:18

24 least are probably fairly soft-spoken. So just 08:18

25 try to make sure that your voice stays elevated so 08:18

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1 at least the mic hears it because as you know, the 08:18  
2 proceedings are being recording by video camera 08:18  
3 and audio as well; all right? 08:18

4 A. Okay. 08:18

5 Q. Now, Dr. Bliesner, one more kind of key 08:18  
6 point. You know, I attended the last session and 08:18  
7 I noticed as I did that, that there were what I 08:18  
8 felt were a fair amount of occasions where you 08:19  
9 didn't really respond to the questions that 08:19  
10 Mr. Moriarty had asked you. And it's obvious from 08:19  
11 your credentials and from your -- just -- just 08:19  
12 dealing with you in the last deposition that 08:19  
13 you're a very intelligent, very capable listener. 08:19  
14 We know that you've been told by Plaintiffs' 08:19  
15 counsel to listen very carefully. So I would ask 08:19  
16 that you really do me the favor of listening and 08:19  
17 making sure that when you answer a question, 08:19  
18 you're actually answering the question that I ask; 08:19  
19 okay? 08:19

20 A. Okay. 08:19

21 Q. I want to talk for a moment about your 08:19  
22 credentials. Do you have a copy of your CV with 08:19  
23 you? 08:19

24 A. Let me check. 08:19

25 Q. Please. And if you don't, I have an 08:19

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1 extra one. 08:19

2 A. I do not. 08:19

3 Q. Okay. Well, I'm going to hand you a 08:20

4 copy. 08:20

5 A. Okay. 08:20

6 Q. Mike, this is Exhibit 93. 08:20

7 Dr. Bliesner, I have handed you a document 08:20

8 that has been marked as Exhibit 93. Have you seen 08:20

9 that document before? 08:20

10 A. Yes. 08:20

11 Q. It's a copy of your CV, your resume; 08:20

12 correct? 08:20

13 A. It is. 08:20

14 Q. You prepared it? 08:20

15 A. I did. 08:20

16 Q. Is it accurate and current? 08:20

17 A. No. 08:21

18 Q. And last time you were asked -- I think 08:21

19 that you gave some testimony that there were a 08:21

20 couple of board memberships that had kind of 08:21

21 changed and there were some minor changes. But as 08:21

22 concerns your education and work experience, is 08:21

23 that CV accurate and current? 08:21

24 A. No. 08:21

25 Q. What is not accurate or current about 08:21

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1 your work experience or education as reflected on 08:21

2 that CV? 08:21

3 A. Yesterday I presented a guest lecture at 08:21

4 the University of South Florida College of 08:21

5 Medicine. 08:21

6 Q. What was the topic of that lecture? 08:21

7 A. The topic was something to the effect 08:21

8 "Consumer Health and GMPs." 08:21

9 Q. Tell me generally the substance of 08:21

10 the -- of the lecture, the subject of the lecture 08:21

11 that you gave yesterday at you said South Florida? 08:21

12 A. University South Florida. 08:21

13 Q. University of South Florida. 08:21

14 A. Yes. 08:21

15 Q. Can you give me a little more detail 08:21

16 than just the topic you just described? 08:21

17 A. Other than pulling up the course outline 08:22

18 and taking a look at it, in general it was an 08:22

19 overview of the drug development process and where 08:22

20 GMPs become pertinent in the drug development 08:22

21 process and an introduction to people who had not 08:22

22 been exposed to the concepts of the GMPs, and some 08:22

23 examples of enforcement and where they could go to 08:22

24 review the GMPs themselves. 08:22

25 Q. Drug development. Does that mean -- 08:22

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1 well, you tell me what that means. What do you 08:22  
2 mean by drug development? 08:22

3 A. Drug development is the process of 08:22  
4 discovering an entity that may have 08:22  
5 pharmacological activity and moving it to a final 08:22  
6 product. 08:22

7 Q. What would you characterize as the 08:22  
8 primary target audience for that lecture? 08:22

9 A. The students in the class were getting a 08:22  
10 masters in biotechnology. 08:22

11 Q. And when you talk about introduction to 08:23  
12 GMPs in the course or in the context of that 08:23  
13 lecture that you gave yesterday, tell me in more 08:23  
14 detail about the types of concepts that you 08:23  
15 presented with respect to the introduction to 08:23  
16 GMPs. 08:23

17 A. I would have to go back and pull up the 08:23  
18 course outline to talk explicitly about it. 08:23

19 Q. Well, you just did it yesterday, right, 08:23  
20 Dr. Bliesner? 08:23

21 A. Uh-huh. 08:23

22 Q. You're a very smart man; right? 08:23

23 MR. KERENSKY: Michael, that's not 08:23  
24 necessary. 08:23

25 MR. ANDERTON: Mike. 08:23

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1 MR. KERENSKY: I object to the form of 08:23  
2 the question. 08:23

3 MR. ANDERTON: You can object and I 08:23  
4 appreciate your objection and you make your 08:23  
5 record obviously, but I asked him what he 08:23  
6 talked about yesterday. Certainly he can 08:23  
7 remember that. 08:23

8 MR. KERENSKY: Well, you certainly need 08:23  
9 to be professional and not say things like 08:23  
10 "You're smart man; right?" That's what I'm 08:23  
11 scolding you about. 08:23

12 MR. ANDERTON: Your scolding is noted, 08:23  
13 Mike. 08:23

14 MR. KERENSKY: Thank you very much. 08:23

15 BY MR. ANDERTON: 08:23

16 Q. Dr. Bliesner, please tell me when you 08:23  
17 described a few moments ago that you gave an 08:24  
18 introduction to GMPs -- 08:24

19 A. Yes. 08:24

20 Q. -- as part of a presentation you made 08:24  
21 yesterday. 08:24

22 A. Yes. 08:24

23 Q. Please give me a description of the 08:24  
24 types of concept that you presented on with 08:24  
25 respect to introduction to GMPs? 08:24

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1           A.     I gave a brief overview of the drug           08:24  
2     development process, I indicated at what point           08:24  
3     GMPs become applicable, talked about the hierarchy       08:24  
4     of the law in a very general sense and where the       08:24  
5     GMPs come into play. I talked about the guidance       08:24  
6     documents and compliance program guidance manuals       08:24  
7     that are available online on the FDA website,           08:24  
8     what's contained generally in those documents, the       08:25  
9     quality systems that are associated with that, and       08:25  
10    the hierarchy with respect to enforcement of           08:25  
11    compliance of the GMPs. Much of the course was           08:25  
12    left as attachments for the students to go and           08:25  
13    look in detail if they sought to.                       08:25  
14           Q.     When you used term -- just to be clear,       08:25  
15    when you used the term GMP as you did in the           08:25  
16    description and the ones you gave before, that is       08:25  
17    an acronym for good manufacturing practices;           08:25  
18    correct?   08:25  
19           A.     It is.                                       08:25  
20           Q.     And that is a subject or a topic that       08:25  
21    emanates from the code of federal regulations           08:25  
22    under the United States code; correct?                   08:25  
23           A.     The GMPs are part of the code of federal       08:25  
24    regulations.   08:25  
25           Q.     You said that you discussed -- that one       08:26

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1 of the things you discussed was at what point GMPs 08:26  
2 become relevant to the drug development process. 08:26  
3 A. (The witness nodded). 08:26  
4 Q. What is that point in your mind? 08:26  
5 A. In my opinion? 08:26  
6 Q. Yes. 08:26  
7 A. The point at which the GMPs become 08:26  
8 applicable is when you start testing the product 08:26  
9 or active in people. 08:26  
10 Q. In people you said? 08:26  
11 A. Yes. 08:26  
12 Q. Does that mean when you are 08:26  
13 participating in some sort of clinical trial? 08:26  
14 A. Yes. 08:26  
15 Q. So GMPs in your mind aren't applicable 08:26  
16 if you're merely doing animal or other lab 08:26  
17 studies; is that correct? 08:26  
18 A. That is correct. 08:26  
19 Q. And when you used the term "drug 08:26  
20 development process," I assume that you're 08:26  
21 talking -- and correct me if my assumption is 08:27  
22 wrong -- I assume that you're talking about a drug 08:27  
23 or an entity as you used that term that has not 08:27  
24 yet been approved for market sale by the FDA. 08:27  
25 A. Not necessarily. 08:27



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1 Q. Under what circumstances can a drug that 08:27  
2 hasn't been developed be approved by the FDA? 08:27

3 A. I don't know if I understand exactly the 08:27  
4 question you're asking. 08:27

5 Q. Well, you described -- you used the term 08:27  
6 "drug development process" and then you clarified 08:27  
7 and added substance to that term by indicating 08:27  
8 that it was the -- the process of taking an entity 08:27  
9 from concept to production and marketing; correct? 08:27

10 A. Correct. 08:28

11 Q. If your -- that process begins before 08:28  
12 FDA approval; correct? 08:28

13 A. Drug development process is very complex 08:28  
14 and it's not, does not fit to one specific case. 08:28  
15 For instance, if you have a generic drug you have 08:28  
16 to do drug development as well but it's already on 08:28  
17 a product that has been approved for market. So 08:28  
18 that could be considered drug development as well, 08:28  
19 as opposed to discovering a new entity and moving 08:28  
20 it forward. 08:28

21 Q. Well, even a generic drug -- 08:28

22 A. Uh-huh. 08:28

23 Q. -- isn't actually -- the brand name is 08:28  
24 approved for marketing; correct? 08:28

25 A. Correct. 08:28

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1 Q. Even the generic drug must go through a 08:28  
2 drug development process and must be submitted to 08:28  
3 the FDA before it can be marketed using an ANDA 08:28  
4 rather than an NDA; correct? 08:28

5 A. Correct. 08:28

6 Q. So this course that you or this 08:28  
7 presentation that you gave yesterday, how long did 08:29  
8 it last? 08:29

9 A. An hour and a half approximately. 08:29

10 Q. How long did you prepare for that 08:29  
11 presentation? 08:29

12 A. Several hours. 08:29

13 Q. What did you do to prepare for that 08:29  
14 presentation? 08:29

15 A. I took my course that I teach routinely 08:29  
16 at client sites, my book, and a course that I also 08:29  
17 teach at conferences routinely, looked at that 08:29  
18 core value that was there, based on input from the 08:29  
19 professor who invited me, trying to target what 08:30  
20 she thought might be useful for the students to be 08:30  
21 exposed in a general sense. 08:30

22 Q. And I -- I understand from your prior 08:30  
23 answer that you distributed some sort of materials 08:30  
24 at that presentation yesterday. 08:30

25 A. I did via Internet link. 08:30

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1 Q. Describe how that works. I haven't been 08:30

2 in college in a long time, so what is the current 08:30

3 practice with respect to distributing course 08:30

4 materials or even a seminar like this? How do you 08:30

5 distribute via Internet link? 08:30

6 A. To answer your first question, I don't 08:30

7 know if there is a general way to do it. 08:30

8 Q. How did you do it? 08:30

9 A. How did I do it? I took the 08:30

10 presentation -- as I told you -- from my basic 08:30

11 course material, targeted it to the needs of the 08:30

12 professor, put in a Power Point presentation, 08:30

13 converted it to a PDF file so it's secure. I 08:30

14 created a folder up on one of my websites that was 08:30

15 blind, I uploaded it and provided a link to the 08:30

16 professor and said that the students could access 08:31

17 it if they'd like. 08:31

18 Q. Okay. And then did you -- I assume then 08:31

19 that you repeated the web address for that link 08:31

20 during the presentation? 08:31

21 A. No. 08:31

22 Q. Okay. So they got it from the professor 08:31

23 and chose to go get it or not? 08:31

24 A. Correct. 08:31

25 Q. Other than -- well, did you bring any of 08:31

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1 the materials that you used in yesterday's 08:31  
2 presentation with you? 08:31

3 A. No. 08:31

4 Q. During the presentation during this 08:31  
5 hour, what -- how much of that was spent on 08:31  
6 manufacturing processes, if any? 08:31

7 A. Could you explain to me what you mean by 08:31  
8 "manufacturing processes"? 08:31

9 Q. Certainly. The drug development 08:31  
10 process -- well, let me back that up. Let me 08:32  
11 start over. 08:32

12 The drug production process involves several 08:32  
13 different components. Developing a drug and 08:32  
14 getting it ready to be manufactured and then 08:32  
15 actually going forward and physically producing 08:32  
16 the product I will characterize as two separate 08:32  
17 components of that process. 08:32

18 Did you discuss during your presentation 08:32  
19 yesterday, that second component, the acts 08:32  
20 associated with physically manufacturing and 08:32  
21 producing a drug product? 08:32

22 A. No because the students -- it was an 08:32  
23 open lecture and the students were allowed to 08:32  
24 drive it where they wanted to go and many of their 08:33  
25 questions were not related to manufacturing. 08:33

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1 Q. Were you planning to discuss that if 08:33  
2 they drove the discussion -- to use your term -- 08:33  
3 in that direction? 08:33

4 A. Brief overview, yes. 08:33

5 Q. Do you know the or can you tell us the 08:33  
6 link, the address for the link to the presentation 08:33  
7 materials for yesterday? 08:33

8 A. Actually, I can't off the top of my 08:33  
9 head. 08:33

10 Q. Can you tell us generally how one might 08:33  
11 get to that link? Is it available through Delphi, 08:33  
12 is it available from claycoachonline? 08:33

13 A. It's available through Delphi in a blind 08:33  
14 web link. 08:33

15 Q. What do you mean by blind web link? 08:33

16 A. The students and the instructor is the 08:33  
17 only ones that have it. 08:33

18 Q. So they need some sort of password or 08:33  
19 invitation? 08:33

20 A. Just the right link to get to the page. 08:33

21 Q. I mean it's not available to anybody who 08:33  
22 happens to go to the Delphi website? 08:33

23 A. No, sir. 08:33

24 Q. When we get a break sometime today, will 08:34  
25 you see what you can do about figuring out how to 08:34

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1 provide me and defense counsel with access to that 08:34

2 link, please? 08:34

3 A. Sure. 08:34

4 Q. Thank you. 08:34

5 A. Uh-huh. 08:34

6 Q. Now other than -- I'll let you make your 08:34

7 note. 08:34

8 Other than this presentation that you gave 08:34

9 yesterday, is the document that is in front of you 08:34

10 and that is marked as Exhibit 93 current with 08:34

11 respect to your education and experience? 08:34

12 A. No. 08:35

13 Q. What else is not on that version of your 08:35

14 CV that relates to your education and experience? 08:35

15 A. I am on a major consulting project right 08:35

16 now, and that's not on the list. 08:35

17 Q. Okay. What's that consulting project? 08:35

18 A. I'm not at liberty to share that with 08:35

19 you because I'm under a confidentiality agreement. 08:35

20 Q. Well, is it going to go on your CV at 08:35

21 some point? 08:35

22 A. Perhaps. 08:35

23 Q. What is the -- without revealing the 08:35

24 client, what is the nature generally of that 08:35

25 consulting project? 08:36

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1 A. The general nature of the consulting 08:36  
2 project is to support laboratory and manufacturing 08:36  
3 investigation review as a third-party independent. 08:36

4 Q. When did that start? 08:36

5 A. June last year. 08:36

6 Q. Of 2010? 08:36

7 A. Yes, sir. 08:36

8 Q. Does that mean that this CV hasn't been 08:36  
9 updated since June 2010 or perhaps before then? 08:36

10 A. I don't know. I'd have to go back and 08:36  
11 look and see when it was last updated. 08:36

12 Q. Other than the consulting project and 08:36  
13 the presentation you gave yesterday, what -- is 08:36  
14 there anything else that's not on this CV that 08:36  
15 relates to your experience or your education? 08:36

16 A. Without going through it line by line, I 08:36  
17 do not see my assistant -- excuse me associate 08:37  
18 professorship at St. Leo University. 08:37

19 Q. Is that a current position? 08:37

20 A. It is. 08:37

21 Q. When did it start? 08:37

22 A. Sometime I want to say approximately 08:37  
23 late spring, early summer of last year. 08:37

24 Q. That's St. Leo University? 08:37

25 A. Yes, sir. 08:38

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1 Q. And it's associate professor? 08:38

2 A. Yes. 08:38

3 Q. What general -- 08:38

4 A. Non-tenured track. 08:38

5 Q. Okay. Describe that generally. What do 08:38

6 you do, what are your responsibilities as an 08:38

7 associate, non-tenured professor at St. Leo 08:38

8 University? 08:38

9 A. I was one of the distance learning 08:38

10 instructors. 08:38

11 Q. What is distance learning? 08:38

12 A. Online education. 08:38

13 Q. So what is your role and what are your 08:38

14 responsibilities? What do you do? 08:38

15 A. I oversaw and taught via Internet 08:38

16 learning packages provided by the university, 08:38

17 introductory to science class. 08:38

18 Q. Any direct interaction with students in 08:38

19 that role? 08:38

20 A. How would you define "direct"? 08:38

21 Q. Well, did you deal with students 08:38

22 face-to-face or in a classroom setting? 08:38

23 A. No. 08:38

24 Q. Did you deal with them exclusively via 08:38

25 online contact? 08:38



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1 A. No. 08:38

2 Q. How did you interact with your students? 08:38

3 A. Online in the course, e-mail and 08:38

4 telephone. 08:39

5 Q. And telephone. 08:39

6 You used or you spoke in the past tense when 08:39

7 you described that position. Is it ongoing? 08:39

8 A. I am -- do have that position within the 08:39

9 organization. I'm not currently teaching a course 08:39

10 because of additional workload. 08:39

11 Q. Is it your expectation that you will 08:39

12 teach it again in the future? 08:39

13 A. Yes. 08:39

14 Q. Do you believe that the university 08:39

15 shares that expectation? 08:39

16 A. I couldn't say. 08:39

17 Q. Are you being paid by St. Leo University 08:39

18 for -- in any way at the moment? 08:39

19 A. At the current moment? 08:39

20 Q. Yes. 08:39

21 A. No. 08:39

22 Q. When did you stop receiving compensation 08:39

23 from St. Leo University? 08:39

24 A. When the semester ended. 08:39

25 Q. Last spring? 08:39

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1 A. Whenever it was. I'd have to go back 08:39

2 and look at that. 08:39

3 Q. Well, there's two semesters in an 08:39

4 academic year. 08:39

5 A. There are several actually, depends, 08:40

6 distant learning, stuff like that. I would have 08:40

7 to go back and look it up. 08:40

8 Q. Give me your best estimate on when that 08:40

9 semester commenced and ended. 08:40

10 A. I really can't tell you when it 08:40

11 started. When it ended it was I think somewhere 08:40

12 in June. 08:40

13 Q. Of 2010? 08:40

14 A. Yes. 08:40

15 Q. Okay. Now, as I look at your CV, I want 08:40

16 to go through that a little bit with you. I see 08:40

17 that your first work experience after you left the 08:40

18 University of Vermont, graduated from the 08:40

19 University of Vermont is with Zeneca; is that 08:40

20 right? 08:41

21 A. Yes. 08:41

22 Q. As an analytical research chemist? 08:41

23 A. That is correct. 08:41

24 Q. And according to your CV, in that role 08:41

25 you developed and validated analytical methods; 08:41

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1 right? 08:41

2 A. That is correct. 08:41

3 Q. Analytical methods describe -- am I 08:41

4 correct that that generally means the method by 08:41

5 which laboratory testing is conducted on some 08:41

6 material that is part of the pharmaceutical -- 08:41

7 part of a pharmaceutical manufacturing process? 08:41

8 A. Can you restate that, please? 08:41

9 Q. Sure. When you use the term "analytical 08:41

10 method," am I correct in my understanding that 08:41

11 that means or is used generally to describe the 08:41

12 method by which laboratory testing is conducted on 08:41

13 something, some entity that is part of a 08:41

14 pharmaceutical manufacturing process -- whether 08:42

15 it's finished product or in-process material or 08:42

16 raw material or -- 08:42

17 A. Packaging material. 08:42

18 Q. Okay. So analytical method is 08:42

19 developing a testing method; correct? 08:42

20 A. I'd say that's accurate. 08:42

21 Q. So your role with Zeneca was entirely in 08:42

22 the laboratory; correct? 08:42

23 A. When you say "entirely in the 08:42

24 laboratory," could you define that, please? 08:42

25 Q. Well did you do any -- you didn't do 08:42

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1 anything it looks like other than perform job 08:42

2 functions related to and around developing, 08:42

3 validating analytical methods; is that accurate? 08:42

4 A. I don't think that's an accurate 08:42

5 statement, no. 08:42

6 Q. Well what else did you do other than 08:42

7 work with developing and validating analytical 08:42

8 methods as your CV says? 08:42

9 A. As it says here, worked closely with 08:43

10 formulation specialists, designed testing 08:43

11 protocols and methods for new dosage forms. 08:43

12 Q. Okay. And that is a -- does that have 08:43

13 anything to do with product manufacturing, the 08:43

14 actual physical manufacturing process? 08:43

15 A. It does. 08:43

16 Q. How? 08:43

17 A. There is actually quite of bit of 08:43

18 extensive formulation development and interaction 08:43

19 with the formulators in the initial dosage form 08:43

20 manufacturing. 08:43

21 Q. Well, what does that have -- 08:43

22 A. Report it back. 08:43

23 Q. What does that have to do with tablet or 08:43

24 product manufacturing? 08:43

25 A. This lays all the basis because this is 08:43

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1 the initial work that's done to get to the final 08:43  
2 validated process in product. 08:43

3 Q. Well, but you're not -- I mean 08:43  
4 Dr. Bliesner your resume says "developing 08:43  
5 analytical methods," not validating manufacturing 08:43  
6 processes. 08:43

7 A. As part of that process you are 08:43  
8 interacting very closely with the formulators and 08:43  
9 the manufacturing folks to test their products and 08:44  
10 be involved in those cross-functional meetings to 08:44  
11 make sure that they're hitting what they're 08:44  
12 supposed to be hitting and when they have problems 08:44  
13 that, you know -- when they're developing 08:44  
14 processes, that you are there to provide 08:44  
15 additional input and feedback with respect to how 08:44  
16 your analyses are reflecting on what they're 08:44  
17 doing. 08:44

18 Q. What type of products did Zeneca make 08:44  
19 while you were in that job? Solid oral dose, 08:44  
20 liquids, gels? 08:44

21 A. As a company at large? 08:44

22 Q. Yeah. 08:44

23 A. Specifically I couldn't -- I'd have to 08:44  
24 go back and look, but it covered the broad lanes 08:44  
25 of product types and formulations. 08:44

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1 Q. And do you believe it included solid 08:44  
2 oral dose? 08:44  
3 A. That, it did. 08:44  
4 Q. Okay. So they were -- were you involved 08:44  
5 in developing and validating analytical methods 08:44  
6 for tablets? 08:44  
7 A. Yes, sir. 08:44  
8 Q. For Digoxin tablets? 08:44  
9 A. No, sir. 08:44  
10 Q. Have you ever been involved with any 08:45  
11 sort of method development or validation with 08:45  
12 respect to Digoxin in any form? 08:45  
13 A. No, sir. 08:45  
14 Q. Your next job with UDL, you described it 08:45  
15 as a principal chemist. And again you indicate -- 08:45  
16 hold on one moment. My apologies, Dr. Bliesner, 08:45  
17 for the interruption. 08:45  
18 A. It's okay. 08:45  
19 Q. You indicate that you are responsible 08:45  
20 for developing and validating analytical methods. 08:45  
21 Tell me what that means. 08:45  
22 A. As we just talked about being part of a 08:45  
23 cross-functional team that supports product 08:45  
24 development to determine the best analytical 08:46  
25 technique to support the required testing and -- 08:46

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1 Q. Well -- I'm sorry. Go ahead. 08:46

2 A. And once the method is developed to a 08:46

3 point where it appears to be validatable, a 08:46

4 validation program protocol is developed and then 08:46

5 validated to prove in fact the method works for 08:46

6 its intended use. 08:46

7 Q. And according to resume, your primary 08:46

8 emphasis was on HPLC method development; is that 08:46

9 right? 08:46

10 A. That's correct. 08:46

11 Q. And HPLC stands for high performance 08:46

12 liquid chromatography; am I correct about that? 08:46

13 A. Yes, and it also stands for high 08:46

14 pressure liquid chromatography. It's a term that 08:46

15 is cross-confused sometimes. It's now becoming 08:46

16 more popular again. 08:46

17 Q. On your resume -- 08:46

18 A. Yes. 08:46

19 Q. -- what does it mean? 08:46

20 A. High performance liquid chromatography. 08:47

21 Q. And that's a method by which a chemical 08:47

22 analysis is performed on some entity; correct? 08:47

23 A. How would you define "chemical 08:47

24 analysis"? 08:47

25 Q. Well, let me -- 08:47

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1 A. Uh-huh. 08:47

2 Q. -- ask you, Dr. Bliesner. What is high 08:47

3 performance liquid chromatography? 08:47

4 A. It's a separation technique. 08:47

5 Q. Separation of what? 08:47

6 A. Components and mixtures. 08:47

7 Q. So it is a technique to analyze 08:47

8 components and mixtures of various drug entities; 08:47

9 correct? 08:47

10 A. Drug products and also to look for 08:47

11 impurities if you will in actives and drug 08:47

12 products. 08:47

13 Q. All right. So it's a lab-based 08:47

14 function, am I correct? 08:47

15 A. That's correct. 08:47

16 Q. Your next -- the next work experience on 08:47

17 your resume is again for UDL and you're listed as 08:48

18 analytical group leader. Do you see that on page 08:48

19 3? 08:48

20 A. I do. 08:48

21 Q. And in that role, you indicate you are 08:48

22 responsible for supervising research chemists. 08:48

23 A. Yes. 08:48

24 Q. Do you see that? 08:48

25 Tell me what you did there. 08:48



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1 A. I was responsible for the people who 08:48  
2 were doing method development and validation and 08:48  
3 testing. 08:48

4 Q. Again, a lab-based function? 08:48

5 A. Yes, and we also interacted with product 08:48  
6 development teams and manufacturing. 08:48

7 Q. Okay. But your primary responsibilities 08:48  
8 were in the lab overseeing research chemists who 08:48  
9 were doing the -- performing the tasks you just 08:48  
10 described; correct? 08:48

11 A. The primary function, yes. 08:48

12 Q. The next position you have listed here 08:48  
13 is analytical laboratory manager. 08:49

14 A. Yes. 08:49

15 Q. You indicate in that role you supervised 08:49  
16 day-to-day operation of lab -- analytical lab 08:49  
17 personnel in various tasks that you list there. 08:49

18 Do you see that? 08:49

19 A. Including methods validation, routine 08:49  
20 analysis, equipment qualification and calibration, 08:49  
21 stability and experimental protocol, yes. 08:49

22 Q. Right. And again that's a lab-based 08:49  
23 position. 08:49

24 A. It is. 08:49

25 Q. And was while you occupied it. 08:49

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1 A. Yes. 08:49

2 Q. The next one, Somerset Pharmaceuticals, 08:49

3 director of analytical research and 08:49

4 development/quality control. You characterize it 08:49

5 as a senior analytical laboratory supervisor. 08:49

6 Is that also a lab-based position? 08:49

7 A. It is, in addition to interacting 08:49

8 extensively with product development people who -- 08:50

9 some of whom reported to me, clinical trial 08:50

10 material manufacturing, dosage formula 08:50

11 manufacturing, some of who reported to me. 08:50

12 Various different -- it was a small company and 08:50

13 everybody wore a lot of hats. In this particular 08:50

14 case we did the whole development bailiwick. 08:50

15 Q. Okay. But your position was so you 08:50

16 interacted with the product development people. 08:50

17 A. Some of who reported to me too. 08:50

18 Q. Okay. Those are also lab-based 08:50

19 positions; correct? 08:50

20 A. Not all of them, no. 08:50

21 Q. What people -- well, did you have any QA 08:50

22 responsibilities? 08:50

23 A. No. QA was a separate function outside 08:50

24 the lab. 08:50

25 Q. And I guess I should go back. Let's go 08:50

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1 back to Zeneca. 08:50

2 A. Okay. 08:50

3 Q. As an analytical research chemist, any 08:50

4 QA responsibilities? 08:51

5 A. No, QA is a separate function. 08:51

6 Q. Okay. 08:51

7 A. Distinct and clear separate function or 08:51

8 should be. 08:51

9 Q. And I understand that. 08:51

10 A. Uh-huh. 08:51

11 Q. But I need to -- I hope you understand, 08:51

12 Dr. Bliesner, I need to establish certain things 08:51

13 for the record. 08:51

14 A. Absolutely. 08:51

15 Q. So with Zeneca -- because as you said QA 08:51

16 is a separate and distinct function from the lab 08:51

17 operations -- 08:51

18 A. Uh-huh. 08:51

19 Q. -- which are typically referred to as 08:51

20 quality control; correct? 08:51

21 A. No. 08:51

22 Q. Well -- 08:51

23 A. Quality control and quality assurance 08:51

24 are two different functions. 08:51

25 Q. That's what I meant. 08:51

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1 A. Yes. 08:51

2 Q. Maybe I didn't say that very clearly. 08:51

3 A. Uh-huh. 08:51

4 Q. Lab functions are typically within the 08:51

5 industry referred to as quality control; is that 08:51

6 correct? 08:51

7 A. That's a fair statement. 08:51

8 Q. Okay. And quality assurance -- or QA as 08:51

9 I've been using that term and as I believe you 08:51

10 understood when I used that term -- 08:51

11 A. Uh-huh. 08:51

12 Q. -- is as you described a separate and 08:51

13 distinct function totally separate from lab 08:51

14 testing and quality control; correct? 08:51

15 A. As an oversight function. Quality 08:52

16 assurance itself is integrated into everything, 08:52

17 including the lab functions you know, review the 08:52

18 data, integrity of data, method development 08:52

19 validation. As far as the title as an oversight, 08:52

20 as a final signoff and a separate pair of eyes 08:52

21 with a different reporting structure, that is the 08:52

22 QA function. 08:52

23 Q. Okay. At Zeneca -- 08:52

24 A. Uh-huh. 08:52

25 Q. -- you had no QA responsibilities; 08:52

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1 correct? 08:52

2 A. No, but GMP responsibilities that are 08:52

3 oversight by QA. 08:52

4 Q. Dr. Bliesner. 08:52

5 A. Yes. 08:52

6 Q. This is what I'm talking about. I asked 08:52

7 you very succinctly whether you had QA 08:52

8 responsibilities. If you would answer that 08:52

9 question and only that question, I would 08:52

10 appreciate it; okay? 08:52

11 Did you have QA responsibilities? 08:52

12 A. As we define QA -- you and I understand 08:52

13 -- quality assurance, separate function, 08:52

14 oversight, no. 08:52

15 Q. Same question with respect to the next 08:52

16 position you have listed, UDL Laboratories and 08:52

17 principal chemist. Did you have any QA 08:52

18 responsibilities? 08:52

19 A. As we've defined it, no. 08:53

20 Q. Same question with respect to the next 08:53

21 UDL position you have as analytical group leader 08:53

22 on your CV. As we've defined QA responsibilities, 08:53

23 did you have any of those QA responsibilities in 08:53

24 that position? 08:53

25 A. No. 08:53

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1 Q. As an analytical laboratory manager for 08:53  
2 Somerset Pharmaceuticals, did you have any QA 08:53  
3 responsibilities? 08:53

4 A. In the formal sense, as QA as we've 08:53  
5 defined it, no. 08:53

6 Q. As the director of analytical research 08:53  
7 and development/quality control for Somerset 08:53  
8 Pharmaceuticals, any QA responsibilities? 08:53

9 A. No. 08:53

10 Q. Moving to the next entry in your CV, 08:53  
11 HPLC, product marketing manager for Restek 08:54  
12 Corporation aPparently at Penn State University. 08:54  
13 Tell me about that position. 08:54

14 A. It was not at Penn State. It's a state 08:54  
15 college. 08:54

16 Q. Is that different? 08:54

17 A. Yes. 08:54

18 Q. Is that not Penn State? 08:54

19 A. Yes. 08:54

20 Q. My apologies. 08:54

21 Tell me about that position. What did you do? 08:54

22 A. Initially, I stepped into a business 08:54  
23 role, business development role, to assist them in 08:54  
24 finding ways to increase their sales of HPLC 08:54  
25 products. 08:54

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1 Q. Okay. And do I understand then that 08:54

2 when you took this position with Restek, you 08:54

3 stepped outside the laboratory and the technical 08:54

4 aspect of the pharmaceutical business and 08:55

5 transitioned to a more business and marketing 08:55

6 role? 08:55

7 A. I don't think that's an accurate 08:55

8 assessment. 08:55

9 Q. Well, why is it not accurate? 08:55

10 A. Because the technical aspects all came 08:55

11 with it in addition to business still. 08:55

12 Q. I understand. But your title is product 08:55

13 marketing manager. And as you described your 08:55

14 responsibilities, you were hired to and did assist 08:55

15 them with trying to increase sales of HPLC 08:55

16 columns; right? 08:55

17 A. I did for a brief period of time. 08:55

18 Q. And your -- what do you mean by a brief 08:55

19 period of time? Does that mean you were only 08:55

20 there for five months, is that what you mean? 08:55

21 A. I only served in that position for five 08:55

22 months. 08:55

23 Q. And then you transitioned to director of 08:55

24 Restek analytical services? 08:55

25 A. I created the position and the title. 08:55

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1 Q. Okay. And backing up to your product 08:55  
2 marketing manager position. 08:56  
3 A. Uh-huh. 08:56  
4 Q. Did you have any QA responsibilities in 08:56  
5 that role? 08:56  
6 A. Yes. 08:56  
7 Q. Really? 08:56  
8 A. For HPLC column manufacturing. 08:56  
9 Q. You had actual oversight responsibility 08:56  
10 for checking the compliance of product 08:56  
11 manufacturing with specifications? 08:56  
12 A. For HPLC columns. 08:56  
13 Q. What do you mean by that? Tell me what 08:56  
14 distinction you're making. 08:56  
15 A. HPLC column is a major component of high 08:56  
16 performance liquid chromatography. 08:56  
17 Q. I understand. 08:56  
18 A. We manufactured HPLC columns at Restek. 08:56  
19 Q. Did Restek manufacture any drug 08:56  
20 products? 08:56  
21 A. No. 08:56  
22 Q. So as director of analytical services, 08:56  
23 that position has -- again is not associated with 08:56  
24 manufacturing drug products, am I correct? 08:57  
25 A. We did not manufacture products on site. 08:57



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1 Q. Did you have any role or responsibility 08:57  
2 for manufacturing -- for any aspect of 08:57  
3 manufacturing any drug product when you were 08:57  
4 employed by Restek? 08:57

5 A. I can't say for sure because we 08:57  
6 consulted to the industry as well and we may have 08:57  
7 performed some consultation with respect to drug 08:57  
8 product manufacturers. 08:57

9 Q. Dr. Bliesner, I asked what your 08:57  
10 experience was, not the company as a whole. 08:57

11 A. No, no. I would have been the one that 08:57  
12 would have been providing that consulting to the 08:57  
13 manufacturing of drug product. I don't recall 08:57  
14 whether we did or not, but we did provide 08:58  
15 consultation in addition to the lab services as 08:58  
16 well. So I can't say definitively that I did or 08:58  
17 did not have input into the drug manufacturing 08:58  
18 process. 08:58

19 Q. What consultation did you yourself 08:58  
20 provide while you were employed by Restek to -- to 08:58  
21 drug product manufacturers? 08:58

22 A. We were in constant contact with them 08:58  
23 because they were our customers for the columns 08:58  
24 and the lab services. So we provided consultation 08:58  
25 on many aspects of the drug development process, 08:58

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1 production, manufacturing. 08:58

2 Q. Are you telling me that you were 08:58

3 involved with developing drug products for other 08:58

4 companies while you were employed by Restek? 08:58

5 A. They were our clients. We consulted 08:58

6 with them if they needed things. 08:58

7 Q. You consulted with them with respect to 08:58

8 various functionality issues of your HPLC columns; 08:58

9 correct? 08:58

10 A. No, not necessarily. We did contract 08:58

11 work, analytical work and product development work 08:58

12 for them as part of the mission. 08:58

13 Q. Well, as part of the mission, as I read 08:58

14 your CV, Dr. Bliesner, that you prepared, it lists 08:59

15 only business functions. It doesn't say anything 08:59

16 about being involved in drug development 08:59

17 processes, does it? 08:59

18 A. If you look at the director of Restek 08:59

19 Analytical Services, it offers analytical method 08:59

20 development, validation, HPLC, GC, education, 08:59

21 training, customer stationary phase design, CGMP 08:59

22 regulatory services and support. That's where 08:59

23 that would fall into. 08:59

24 Q. And your testimony is that you performed 08:59

25 those functions while you were at Restek? 08:59

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1 A. Some of them, yes. 08:59

2 Q. What do you mean by some of them? 08:59

3 A. I interacted primarily with the client 08:59

4 as the first line. 08:59

5 Q. You mean you were the first line -- you 09:00

6 were Restek's front line person interacting with 09:00

7 the client. Is that what you mean by that? 09:00

8 A. Yes, sir. For this division, Restek 09:00

9 Analytical Services. 09:00

10 Q. Well, your job duties and 09:00

11 responsibilities as you described them included 09:00

12 market research, drafting a business plan, and 09:00

13 obtaining funding and approval from Restek. 09:00

14 You go on to describe what Restek does, but 09:00

15 you don't say anything about your -- about you 09:00

16 being involved in any of the analytical method 09:00

17 development consultation, do you? 09:00

18 A. If I was to list this here, the document 09:00

19 would be about 25 pages long for all the different 09:00

20 jobs that I've had. 09:00

21 Q. Dr. Bliesner, I'm merely pointing out 09:00

22 that you described your job duties and 09:00

23 responsibilities strictly in a business capacity; 09:00

24 is that right? 09:00

25 A. No, that's not correct. 09:00

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1 Q. Your statement on here says that you 09:01  
2 were responsible for conception, design, building, 09:01  
3 staffing, and qualification of Restek Analytical 09:01  
4 Services. 09:01

5 A. That is correct. 09:01

6 Q. And you go on to say that included 09:01  
7 conducting market research, drafting a business 09:01  
8 plan, and obtaining funding. 09:01

9 A. That is correct. 09:01

10 Q. You don't say anything about interacting 09:01  
11 with clients on assisting with development of 09:01  
12 analytical methods. 09:01

13 A. As I said, if I put everything down I 09:01  
14 did here, the document would be 25 pages long. 09:01  
15 This is a summary resume to send out to people. 09:01

16 Could I interrupt for a second, please? 09:01

17 Q. Would you like to take a break? 09:01

18 A. Yes, please. 09:01

19 MR. ANDERTON: Absolutely. 09:01

20 THE VIDEOGRAPHER: The time is 9:01 a.m. 09:01

21 We're going off the record briefly. 09:01

22 (Short break) 09:12

23 THE VIDEOGRAPHER: The time is 9:12 a.m. 09:12

24 We're back on the record. This is the 09:13

25 beginning of tape two. 09:13

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1 BY MR. ANDERTON: 09:13

2 Q. Dr. Bliesner, -- hey Mike. Mike? 09:13

3 MR. KERENSKY: Yes. 09:13

4 MR. ANDERTON: If you're going to be 09:13

5 typing -- 09:13

6 MR. KERENSKY: All right. I'll put it 09:13

7 back on mute. Happens all the time. I'm 09:13

8 sorry. 09:13

9 MR. ANDERTON: That's all right. 09:13

10 BY MR. ANDERTON: 09:13

11 Q. All right. Dr. Bliesner, we were 09:13

12 discussing various things on your resume and we 09:13

13 left off -- or your CV. We left off with director 09:13

14 of analytical services for Restek. 09:13

15 A. Restek, yes. 09:13

16 Q. Restek. Sorry. And the State College 09:13

17 of Pennsylvania. The next -- well, let me let me 09:13

18 ask one final question about that position. 09:13

19 The consultation that you described being 09:14

20 involved with in that position was primarily 09:14

21 consultation -- well, was exclusively consultation 09:14

22 related to lab-based activities; correct? 09:14

23 A. No, I don't think you'd say that 09:14

24 exclusively. We went into a lot of different 09:14

25 client sites, interacted with groups of folks at 09:14

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1 the client sites which included, you know, product 09:14  
2 development, manufacturing types, lab types, 09:14  
3 usually looking for a source of additional 09:14  
4 information in addition to solving problems. 09:14

5 Q. Primarily lab-based activities that you 09:14  
6 were giving consultation on? 09:14

7 A. I wouldn't say primarily. 09:14

8 Q. Well, you sold -- 09:14

9 A. It was very broad-based in our approach 09:14  
10 in how we were trying to line up customers. 09:14

11 Q. Well, you sold HPLC columns; right? 09:14

12 A. And services. 09:15

13 Q. And what type of services? What do you 09:15  
14 mean by services? 09:15

15 A. That's what Restek Analytical Services 09:15  
16 was all about. It wasn't just about selling HPLC 09:15  
17 columns. It was about selling contract analytical 09:15  
18 services and providing consulting services -- GMP 09:15  
19 training, those types of things -- to the industry 09:15  
20 so they could partner with us and be interested in 09:15  
21 buying the columns and we would validate the 09:15  
22 methods. 09:15

23 Q. Analytical services again relates to lab 09:15  
24 functions; right? 09:15

25 A. It wasn't necessarily all analytical 09:15

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1 services because there was formulation development 09:15

2 discussions that went on in there as well. 09:15

3 Q. When you left Restek and went to work -- 09:15

4 the next position listed on your CV is 09:15

5 vice-president of operations for Laboratory 09:15

6 Management Systems in New Castle, Delaware. 09:15

7 A. That's correct. 09:15

8 Q. According to your CV, you created and 09:16

9 drove sales and marketing plans; is that right? 09:16

10 A. As one part of my responsibilities, yes. 09:16

11 Q. What else did you do? 09:16

12 A. Primary responsibility took up the 09:16

13 lion's share of the time as I was an active 09:16

14 consultant with the Wyeth and Schering Plough 09:16

15 consent decrees. 09:16

16 Q. Doing what? 09:16

17 A. Being part of the FDA-mandated 09:16

18 third-party expert contingent consult, where we 09:16

19 went in and did very detailed, thorough 09:16

20 assessments, documented the findings, developed 09:16

21 corrective actions and went back in and did 09:16

22 verification and then backed the actions that had 09:16

23 been put into place that were stable -- were 09:16

24 verifiable and sustainable from a quality systems 09:16

25 standpoint. 09:16

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1 Q. Wyeth and who else? 09:16

2 A. Schering Plough. 09:16

3 Q. Schering Plough. Both were under 09:16

4 consent decrees? 09:16

5 A. They were. 09:17

6 Q. Did you visit both of those companies 09:17

7 while you were employed by Laboratory Management 09:17

8 Systems? 09:17

9 A. When you say "visit," they're very large 09:17

10 organizations that have many different sites. 09:17

11 Q. Did you visit any of them? 09:17

12 A. Yes, sir. 09:17

13 Q. For both companies? 09:17

14 A. Yes, sir. 09:17

15 Q. And -- 09:17

16 A. The visit actually was on site 09:17

17 extensively for some of them. 09:17

18 Q. And so you were part of what I'll 09:17

19 characterize as the remediation activities for 09:17

20 both of those companies? 09:17

21 A. I wouldn't characterize it as such. 09:17

22 Q. What's wrong with my term remediation 09:17

23 activities? 09:17

24 A. Remediation assumes that you've already 09:17

25 found everything that was wrong. 09:17



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1 Q. Okay. But there were certainly 09:17

2 remediation activities. 09:17

3 A. That followed, yes. 09:17

4 Q. Well, if you're under a consent decree, 09:17

5 there are certain things that have already been 09:17

6 identified; right? 09:17

7 A. The FDA would have found and documented 09:17

8 through 483s, warning letters, and presented an 09:17

9 EIR, continuing deficiencies, yes. 09:18

10 Q. And tell me about the process that 09:18

11 you -- and let's ask first about Wyeth. 09:18

12 A. Uh-huh. 09:18

13 Q. Tell me about the process that you 09:18

14 followed as you provided consulting services to 09:18

15 them to help them address the issues that were 09:18

16 raised by the consent decree and the underlying 09:18

17 regulatory activities that resulted in that 09:18

18 consent decree. 09:18

19 A. Okay. 09:18

20 Q. What process did you follow? 09:18

21 A. As a global? 09:18

22 Q. Yeah, generally. 09:18

23 A. Generally. 09:18

24 Q. And then I'll ask more specific 09:18

25 questions based on your response. 09:18

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1 A. First of all, each consent decree as I'm 09:18  
2 sure you know is an individually negotiated plan. 09:18

3 Q. Understood. 09:18

4 A. In the Wyeth consent decree, we first 09:18  
5 came in and did very detailed assessments of the 09:18  
6 major quality system elements. 09:18

7 Q. Which involved what? 09:18

8 A. Going into individual departments -- 09:19  
9 laboratories, manufacturing areas, packaging 09:19  
10 areas -- usually in teams of two people and asking 09:19  
11 questions, performing interviews, looking at data, 09:19  
12 looking at protocols, the whole plethora of 09:19  
13 activities for each one of the quality system 09:19  
14 elements. Document them. 09:19

15 Q. Looking at data and looking at 09:19  
16 protocols, two things that you identified in that 09:19  
17 response. What do each of those mean? Looking at 09:19  
18 what type of data, looking at what type of 09:19  
19 protocols? 09:19

20 A. It really depended because it was a huge 09:19  
21 organization and addressed many different 09:19  
22 components. So you would be assigned a department 09:19  
23 for instance that you could go in on for a 09:19  
24 particular week and you would determine their work 09:19  
25 flow, how they conducted business, how they 09:19

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1 documented things, how data was collected, and you 09:19  
2 would go soup to nuts, systematic approach, 09:19  
3 looking through to see if they, in fact, had 09:19  
4 quality systems or any systems in place, whether 09:20  
5 they had procedures in place, whether people were 09:20  
6 trained and just in a laboratory notebook document 09:20  
7 all these findings and go back and write them up 09:20  
8 as findings from the assessment, very similar to 09:20  
9 what the FDA would do on a 483. A very extensive, 09:20  
10 heavy-duty process. 09:20  
11 That was only the first part. 09:20  
12 Q. What was the second part? 09:20  
13 A. The second part was a compilation of all 09:20  
14 of the findings into a report. 09:20  
15 Q. The findings meaning your analysis of 09:20  
16 the data as you described it and protocols that 09:20  
17 you reviewed and all the other information that 09:20  
18 you reviewed. 09:20  
19 A. Systems in general; okay? Quality 09:20  
20 system, laboratory control system, product system, 09:20  
21 packaging, labeling, all of those different 09:20  
22 things. You know, it was a detailed assessment 09:20  
23 and that would include reviewing training records 09:20  
24 for instance for the individuals that are there, 09:20  
25 looking at, you know, production records. 09:20

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1 Everything you would imagine that constitutes a 09:21  
2 modern pharmaceutical manufacturing system -- down 09:21  
3 to excruciating details. 09:21

4 Q. That was all part of your consulting? 09:21

5 A. Yes. We had a 150 people team initially 09:21  
6 on the one site with Wyeth. 09:21

7 Q. How long did that process take? 09:21

8 A. The initial assessment? 09:21

9 Q. Yes. 09:21

10 A. The initial site where we started -- 09:21  
11 it's been a long time. The assessment ran 09:21  
12 somewhere in the neighborhood of approximately 09:21  
13 three months. 09:21

14 Q. With 150 people on site for three 09:21  
15 months? 09:21

16 A. Absolutely. 09:21

17 Q. 150 laboratory management systems 09:21  
18 employees on Wyeth's site for three months? 09:21

19 A. We were subcontractors as part of a 09:21  
20 team. 09:22

21 Q. Okay. As you performed that 09:22  
22 assessment. 09:22

23 A. Uh-huh. 09:22

24 Q. That's a correct term? 09:22

25 A. Yes. 09:22

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1 Q. Is that the same thing as an audit? 09:22

2 A. I don't think I would define it like 09:22

3 that, but... 09:22

4 Q. Well -- 09:22

5 A. It's the same process, yeah. 09:22

6 Q. Okay. So if I describe the process that 09:22

7 you just described. 09:22

8 A. Uh-huh. 09:22

9 Q. 150 people on site for three months, 09:22

10 soup to nuts, virtually everything you can think 09:22

11 of with respect to a manufacturing and production 09:22

12 process. 09:22

13 A. Uh-huh. 09:22

14 Q. That's an accurate description of what 09:22

15 you guys -- the activity you undertook. 09:22

16 A. Everything. All of the components of 09:22

17 the quality systems that constituted that. 09:22

18 Q. So if I described that process as an 09:22

19 audit, would that be an accurate or a fair 09:22

20 characterization? 09:22

21 A. Perhaps. There's confusion in the 09:23

22 industry in general about what's an assessment, 09:23

23 what's a self-assessment, what's an audit, what's 09:23

24 an inspection, so... 09:23

25 Q. I understand. 09:23

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1 A. Yes. 09:23

2 Q. I'm asking you. 09:23

3 A. To me, personally? 09:23

4 Q. Yes. 09:23

5 A. An audit is a like the agency coming in 09:23

6 and doing something from the outside. It's not 09:23

7 necessarily open and collaborative. This 09:23

8 assessment was full disclosure from all employees 09:23

9 and everything. You know, sit down, tell us 09:23

10 what's wrong, tell us everything that's there, you 09:23

11 know, everybody volunteering information. I 09:23

12 consider that to be different than an audit. 09:23

13 Q. Well, when you -- so you then used the 09:23

14 term audit and believe it is best used only to 09:23

15 apply to a -- a -- I guess I'll characterize that 09:23

16 as third-party or just the FDA? I mean I'm not 09:24

17 sure I understand the distinction. 09:24

18 A. And to be perfectly honest with you, 09:24

19 there's confusion in the industry too. So I don't 09:24

20 know if your statement is the best description of 09:24

21 it. 09:24

22 Q. Well, then I mean what is -- what is the 09:24

23 difference between an audit and the assessment 09:24

24 that you just described? 09:24

25 A. An audit, in my experience, they usually 09:24

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1 come in the form of a corporate entity, quality 09:24  
2 assurance coming down to a specific site and 09:24  
3 performing a compliance assessment that's an audit 09:24  
4 to try to determine stuff. 09:24

5 When corporate comes down to a site, it isn't 09:24  
6 necessarily a free and open sharing of things with 09:24  
7 individuals because it's corporate. So that is 09:24  
8 how audits work per se. 09:24

9 An assessment is when -- I've actually just 09:24  
10 recently finished a very extensive one where we 09:24  
11 would sit down and it's full, open, and honest 09:24  
12 disclosure, everybody is laying things out because 09:24  
13 you really want to get to the root cause during an 09:24  
14 assessment, self-assessment, to find out what's 09:25  
15 broken and what potential corrective actions may 09:25  
16 be and how to implement corrective and preventive 09:25  
17 actions and verify the actions, collecting these 09:25  
18 data, all the things we've described. 09:25

19 Q. So then as you understand and use, as 09:25  
20 you used the term audit, does that mean you don't 09:25  
21 think it's -- that there's as much disclosure and 09:25  
22 openness when an audit is being conducted? 09:25

23 A. I would say that's a fair assessment, 09:25  
24 yes. Because people volunteer information during 09:25  
25 an assessment, but if the FDA comes in to do an 09:25

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1 audit, people don't volunteer information. 09:25

2 Q. Well, if corporate comes in to do an 09:25

3 audit, they volunteer information don't they, 09:25

4 typically? 09:25

5 A. It's restrained in my experience. 09:25

6 Q. Do you feel that the people who are the 09:25

7 subject of either an assessment or an audit make 09:25

8 that type of distinction or do they kind of look 09:25

9 at it as though it's corporate or the FDA or a 09:25

10 third party asking questions about what they do 09:26

11 and how they do it? 09:26

12 A. I don't know if I really understand the 09:26

13 question. 09:26

14 MR. ANDERTON: Can you read that back, 09:26

15 Phil. 09:26

16 THE WITNESS: I think there's a couple of 09:26

17 questions in there. I think people in 09:26

18 general -- again, confusion on terms. We'll 09:26

19 use my definition audit, a third party coming 09:26

20 in or a corporate entity, something like that, 09:26

21 as opposed to assessment, being 09:26

22 self-assessment you want to uncover 09:26

23 everything. Those two distinctions. I think 09:26

24 people respond to audits and assessments, 09:26

25 self-assessments differently, yes. And the 09:26



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1 reason for that is that audits -- corporate, 09:26  
2 FDA or whatever -- obviously carry tremendous 09:27  
3 consequences. 09:27

4 BY MR. ANDERTON: 09:27

5 Q. Okay. When you performed this 09:27  
6 assessment of Wyeth with 150 people on site for 09:27  
7 three months. 09:27

8 A. About three months. 09:27

9 Q. Okay. Fair enough. 09:27

10 A. And there are several other sites that 09:27  
11 were involved as well. 09:27

12 Q. Fair enough. Well, when your team 09:27  
13 performed this assessment that lasted 09:27  
14 approximately three months at various locations of 09:27  
15 Wyeth and you did your soup to nuts review, did 09:27  
16 you have access to any information that you 09:27  
17 wanted? 09:27

18 A. By agreement and communication with the 09:27  
19 company, the official position was yes, we were to 09:27  
20 have access to any information we wished. 09:27

21 Q. And by that you mean that was a 09:27  
22 condition of you doing the assessment because it's 09:27  
23 necessary to do it properly? 09:27

24 A. That's correct. 09:28

25 Q. And that's typical when you do that type 09:28

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1 of assessment; correct? You need to have full 09:28  
2 access to whatever documents you think are 09:28  
3 necessary and appropriate in order to properly 09:28  
4 perform an assessment as you've described; is that 09:28  
5 right? 09:28

6 A. "Typical" is a very broad term. I don't 09:28  
7 know if I'd necessarily use it. Because, again, 09:28  
8 each consent decree as you know is negotiated 09:28  
9 differently and may involve certain departments 09:28  
10 within the larger company that may or may not 09:28  
11 necessarily be involved with the consent decree or 09:28  
12 initially involved in the consent decree for 09:28  
13 example. 09:28

14 Q. The consent decree -- 09:28

15 A. Yes. 09:28

16 Q. -- or if it's another regulatory 09:28  
17 document is a starting point for the assessment; 09:28  
18 correct? 09:28

19 A. When you say "another regulatory 09:28  
20 document." 09:28

21 Q. Might be a 483, might be a warning 09:28  
22 letter. You've done consulting engagements where 09:28  
23 the company wasn't involved in a negotiated 09:29  
24 consent decree; correct? 09:29

25 A. That's correct. 09:29

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1 Q. And sometimes you're doing an assessment 09:29

2 based on an FDA warning letter; correct? 09:29

3 A. Or a preparation for a preapproval 09:29

4 inspection for FDA, another example. 09:29

5 Q. But to answer my question, it's true 09:29

6 that you've done assessments where a company 09:29

7 receives a warning letter, they hire you or people 09:29

8 that you work with and for and they ask you to do 09:29

9 what you've described as an assessment on the 09:29

10 basis of that warning letter; is that true? 09:29

11 A. That is correct, yes. 09:29

12 Q. All right. And have you also done 09:29

13 assessments on the basis of FDA 483s? 09:29

14 A. Specifically 483s? 09:29

15 Q. Yeah. 09:29

16 A. No. 09:29

17 Q. Okay. When you -- when you do those -- 09:29

18 and I believe last time you testified that you've 09:29

19 done about five -- and I think the term that you 09:29

20 used was audit rather than assessment, you've done 09:30

21 about five GMP compliance audits in your career. 09:30

22 Does that sound about right? 09:30

23 A. Let me think about it for a second. 09:30

24 Q. Take your time. 09:30

25 A. Yeah, about five or six. 09:30

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1 Q. Back to the assessments that you said 09:31  
2 you've done for or on the basis of an FDA warning 09:31  
3 letter. When you undertook those engagements, was 09:31  
4 it also a condition of your engagement that you 09:31  
5 would have access to the documents you and your 09:31  
6 team felt were necessary to review in order to 09:31  
7 conduct the assessment? 09:31

8 A. In the circumstance where it was just a 09:31  
9 warning letter, the project did not start out as 09:31  
10 we're bringing you in to do an assessment. It 09:31  
11 evolved into that. 09:31

12 Q. And when it did -- 09:31

13 A. Yes. 09:31

14 Q. -- did you insist on having full access 09:31  
15 to the documents you deemed necessary to properly 09:32  
16 conduct your assessment? 09:32

17 A. We didn't insist. We just expected 09:32  
18 because it was the next evolution for the client 09:32  
19 to ask for it that we would have what we needed. 09:32

20 Q. Would you do an assessment if a 09:32  
21 potential client said no, we're not going to give 09:32  
22 you access to certain documents? Production 09:32  
23 records for example. 09:32

24 A. Would we do the assessment? 09:32

25 Q. Yeah. 09:32

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1 A. Depends on what the client wants out of 09:32  
2 the assessment. 09:32

3 Q. Well, if a client hired you to assess 09:32  
4 GMP compliance. 09:32

5 A. Okay. In general. 09:32

6 Q. Yes. 09:32

7 A. Uh-huh. 09:32

8 Q. And said I'm not going to -- I want you 09:32  
9 to do it without looking at production records, 09:32  
10 would you do that? 09:32

11 A. If it was to be a comprehensive review 09:32  
12 of compliance with the GMPs using a quality 09:32  
13 systems based approach, we would inform the client 09:32  
14 that unless we had access to those records, that 09:32  
15 they wouldn't be getting what they were asking 09:33  
16 for. 09:33

17 Q. So they wouldn't be getting a 09:33  
18 comprehensive, accurate assessment of GMP 09:33  
19 compliance? 09:33

20 A. Any my opinion, if they did not give 09:33  
21 open access to the records, yes. 09:33

22 Q. To the production records. That's the 09:33  
23 records I was talking about. 09:33

24 A. Well, specifically -- it depends what 09:33  
25 the client wants; okay? If the client wants the 09:33

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1 whole thing, then access to production records 09:33  
2 would probably be something you would want to have 09:33  
3 access to. 09:33  
4 Q. And I want -- I guess I want to make 09:33  
5 sure this is clear because I was talking about 09:33  
6 production records. 09:33  
7 A. Okay. I misunderstood you. 09:33  
8 Q. I said it -- I thought I said it pretty 09:33  
9 clearly. 09:33  
10 A. Sorry. 09:33  
11 Q. If a client hired you to assess its 09:33  
12 general GMP compliance. 09:33  
13 A. Right. 09:33  
14 Q. And said, I don't want to give you -- I, 09:33  
15 client, don't want to give you access to the 09:33  
16 production records, you can do it from other 09:33  
17 records, could you properly do that? 09:33  
18 A. If it was a -- included an assessment of 09:33  
19 the production system? 09:33  
20 Q. Yes. 09:33  
21 A. No, you couldn't. 09:34  
22 Q. Couldn't do it? 09:34  
23 A. In my opinion, no. 09:34  
24 Q. Okay. In your work experience, have you 09:34  
25 ever worked in manufacturing? 09:34

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1 A. On the floor in manufacturing? 09:34

2 Q. Yes. 09:34

3 A. During product development, yes. 09:34

4 Q. What did you do? 09:34

5 A. Helped troubleshoot a fluid bed dryer. 09:34

6 Q. Tell me more about that. 09:34

7 A. I was, had one of my individuals at the 09:34

8 Somerset facility. He was working with a Glatt, 09:34

9 G-L-A-T-T. It's a fluid bed coater if you will. 09:34

10 And he was having a lot of problems with it and 09:34

11 everything else and asked me if I would come in 09:35

12 and watch him go through the process and if I 09:35

13 could offer any suggestions on how to correct it. 09:35

14 Q. Okay. Have you ever actually -- other 09:35

15 than a support functionality as, you know, since 09:35

16 it's troubleshooting like that -- 09:35

17 A. Uh-huh. 09:35

18 Q. -- have you ever actually had daily 09:35

19 responsibilities in the manufacturing context? 09:35

20 A. No. 09:35

21 Q. In a packaging context? 09:35

22 A. As in a production environment package? 09:35

23 Q. Yes. 09:35

24 A. No. 09:35

25 Q. In a QA context. Have you ever been 09:35

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1 directly in the QA operation or functionality? 09:35

2 A. As we defined it for QA? 09:35

3 Q. Yes. 09:35

4 A. Separate oversight? 09:35

5 Q. Yeah. 09:35

6 A. No. 09:35

7 Q. Do you have a copy of your report, 09:36

8 Dr. Bliesner? 09:36

9 A. I do. 09:36

10 Q. All right. Why don't you get it in 09:36

11 front of you -- 09:36

12 A. Okay. 09:36

13 Q. -- please. And, Mike, this is Exhibit 09:36

14 92. I believe is the version we were looking at 09:36

15 last time. 09:36

16 A. Now, this is my personal version so I 09:36

17 don't have a copy of the 92 that you're working 09:36

18 off of. 09:36

19 Q. Well, let's make sure, then. 09:36

20 A. I know there was a couple of page 09:36

21 discrepancies before. 09:36

22 Q. I understand. So we're going to hand 09:36

23 you a copy of Exhibit 92. 09:36

24 A. Okay. 09:36

25 Q. Turn to page -- well, what is my page. 09:36



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1 A. It's 92. We should be okay now. 09:37

2 Q. Okay. Fair enough. Yeah, these should 09:37

3 be the same actually. 09:37

4 A. Yes. 09:37

5 Q. So. 09:37

6 A. It was just there was two different 09:37

7 exhibits before and they were a page off because 09:37

8 of formatting or something like that. 09:37

9 Q. Okay. 09:37

10 A. With respect to my format. 09:37

11 Q. So turn to page 21. 09:37

12 A. Okay. 09:37

13 Q. And paragraph number 8 on page 21 which 09:37

14 has the heading "conclusions." 09:37

15 Do you see that? 09:37

16 A. Yes. 09:37

17 Q. And in that paragraph, you issue, I 09:37

18 guess, your opinion in this case; is that 09:37

19 accurate? 09:37

20 A. It is my opinion based on the documents 09:37

21 I reviewed. 09:37

22 Q. Okay. And your opinion is that 09:37

23 adulterated drug product made it to the 09:38

24 marketplace. 09:38

25 Is that a fair characterization of your 09:38

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1 opinion? 09:38

2 A. We know it did because the pharmacist 09:38

3 found product that was double-thick. 09:38

4 Q. Well, when you give that response, are 09:38

5 you talking about the 2004 circumstances where a 09:38

6 pharmacist reported a double-thick tablet? 09:38

7 A. I'd have to go back through and take a 09:38

8 look. 09:38

9 Q. Please do. 09:38

10 A. Do you have a sticky by chance? 09:40

11 Q. Yes. I don't but? 09:40

12 MS. DREWES: I do. 09:40

13 THE WITNESS: Can I have? 09:40

14 MS. DREWES: Sure. 09:40

15 THE WITNESS: Bunches of them, please. 09:40

16 MS. DREWES: Here. 09:40

17 THE WITNESS: Just to make sure. Else 09:40

18 you know me, I'll be writing all over this 09:40

19 thing. 09:40

20 BY MR. ANDERTON: 09:46

21 Q. Dr. Bliesner, are you re-reading your 09:46

22 report? 09:46

23 A. No, I'm just being careful, make sure 09:46

24 that I pull out the information that you wanted. 09:46

25 Q. Well, I asked you what you were 09:46

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1 referring to when you said "we know." 09:46

2 A. Uh-huh. 09:46

3 Q. "Product made it to market." 09:46

4 A. Uh-huh. And you asked me to identify 09:46

5 all those circumstances in the report so that's 09:46

6 what I'm doing. Would you like me to stop? 09:46

7 Q. Well, how many do you think there are? 09:46

8 A. I'm going to finish reviewing the report 09:46

9 and then I'll tell you. 09:46

10 Q. Answer my question. How many do you 09:46

11 think there are? 09:46

12 A. I'm not going to say off the top of my 09:46

13 head. 09:46

14 Q. Did you -- did you prepare for this 09:46

15 deposition, Dr. Bliesner? 09:46

16 A. Today? 09:46

17 Q. Yes. 09:46

18 MR. KERENSKY: Mike, that's an 09:46

19 unnecessary question. You don't have to 09:46

20 answer that, Mr. Bliesner. 09:46

21 MR. ANDERTON: Are you instructing him 09:46

22 not to answer that, Mike? 09:46

23 MR. KERENSKY: He's not because that's an 09:46

24 unprofessional question. 09:46

25 MR. ANDERTON: Are you instructing him 09:46

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1 not to answer? 09:46

2 MR. KERENSKY: Yes. What you're doing -- 09:46

3 MR. ANDERTON: On what basis? 09:46

4 MR. KERENSKY: Change the question, Mike. 09:46

5 MR. ANDERTON: On what basis are you 09:47

6 instructing him not to answer? 09:47

7 MR. KERENSKY: Because it's harassing. 09:47

8 MR. ANDERTON: I'm not harassing him. 09:47

9 I'm asking him -- I'm going to get into this 09:47

10 line of questioning whether at this moment or 09:47

11 some other time. I'm allowed to inquire what 09:47

12 he did to prepare. 09:47

13 MR. KERENSKY: All right. Maybe a later 09:47

14 time when you're actually asking those 09:47

15 questions we'll answer that question. 09:47

16 MR. ANDERTON: No, Mike, you cannot 09:47

17 instruct a witness not to answer because you 09:47

18 don't like the timing of the question. 09:47

19 MR. KERENSKY: Yes, I can. 09:47

20 MR. ANDERTON: No, you cannot. 09:47

21 MR. KERENSKY: Let him finish answering 09:47

22 the question you've asked. 09:47

23 MR. ANDERTON: I'm asking a different 09:47

24 question now. Dr. Bliesner -- 09:47

25 THE WITNESS: Can I get some water? 09:47

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1 MR. ANDERTON: Yes, you may get some 09:47  
2 water. Let's go off the record for a moment. 09:47  
3 THE VIDEOGRAPHER: The time is 9:47 a.m. 09:47  
4 We're going off the record briefly. 09:47  
5 (Short break) 09:48  
6 THE VIDEOGRAPHER: The time is 9:48 a.m. 09:48  
7 We are back on the record. 09:48  
8 BY MR. ANDERTON: 09:48  
9 Q. Dr. Bliesner, I'm going to let you 09:48  
10 continue your review, but I'm going to briefly ask 09:48  
11 you a few questions. 09:48  
12 Did you prepare for this deposition today? 09:48  
13 A. Some. 09:48  
14 Q. What did you do to prepare? 09:48  
15 A. At Mike's suggestion I took all of the 09:48  
16 boxes and stuff that were disorganized from the 09:48  
17 last deposition -- but I did nothing with them -- 09:48  
18 and put them in order. 09:48  
19 Q. Did you do anything else besides 09:48  
20 organize your boxes? 09:48  
21 A. Reviewed the report. 09:48  
22 Q. You did review the report? 09:48  
23 A. Uh-huh. 09:49  
24 Q. When did you do that? 09:49  
25 A. This morning. 09:49

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1 Q. This morning? 09:49

2 A. Uh-huh. 09:49

3 Q. When you got here at 7:30 or so? 09:49

4 A. Uh-huh. 09:49

5 Q. What time did you get up to review your 09:49

6 report this morning? 09:49

7 A. I woke up at 3:30 this morning. 09:49

8 Q. Do you typically wake up at 3:30? 09:49

9 A. Unfortunately I have to say this, but 09:49

10 yes, I do. 09:49

11 Q. It is unfortunate. 09:49

12 A. Middle age. 09:49

13 Q. Did you -- did you review the entire 09:49

14 report this morning? 09:49

15 A. No. 09:49

16 Q. Well, what parts of it did you review 09:49

17 and what the purpose of your reviewing the report 09:49

18 this morning, what were you looking for? 09:49

19 A. Just glancing through, familiarize 09:49

20 myself with some of the attachments. 09:49

21 Q. Before organizing -- other than 09:49

22 organizing your boxes and reading your report this 09:49

23 morning, what else did you do to prepare for this 09:49

24 deposition today? 09:49

25 A. Preparation, that was it. I didn't do 09:50

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1 much at all. 09:50

2 Q. Didn't do much at all. Did you meet 09:50

3 with any of the lawyers for the Plaintiffs in this 09:50

4 litigation Mr. Kerensky, Miss Johnson, any of 09:50

5 those lawyers? 09:50

6 A. When you say "meet." 09:50

7 Q. Did you meet with them in person? 09:50

8 A. No. 09:50

9 Q. Did you speak to them on the telephone? 09:50

10 A. I spoke with them but it didn't have 09:50

11 much to do with prep. 09:50

12 Q. Did you speak to them on the telephone? 09:50

13 A. I did speak with Miss Johnson. 09:50

14 Q. Miss Johnson? 09:50

15 A. Yeah, briefly, and confirmed with 09:50

16 Mike -- I can never pronounce. 09:50

17 Q. Kerensky. 09:50

18 A. Kerensky, yeah. 09:50

19 MR. ANDERTON: I got your back, Mike. 09:50

20 MR. KERENSKY: Got it. 09:50

21 BY MR. ANDERTON: 09:50

22 Q. You spoke with Miss Johnson how many 09:50

23 times? 09:50

24 A. Once. 09:50

25 Q. How long did that conversation last? 09:50

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1 A. About a minute and a half. 09:51

2 Q. That was -- that was since January 25th, 09:51

3 between January 25th and today? 09:51

4 A. No. You asked yesterday in preparation 09:51

5 for this. 09:51

6 Q. No, I said before this deposition. I 09:51

7 was not limiting my question to yesterday. 09:51

8 A. Okay. Before this deposition? 09:51

9 Q. Yeah. So let's break this down, okay, 09:51

10 Dr. Bliesner. 09:51

11 A. Uh-huh. 09:51

12 Q. I need you to listen very carefully, 09:51

13 please. 09:51

14 A. Right. I am. 09:51

15 Q. Since you were -- since we began this 09:51

16 deposition and opened the record on January 25th 09:51

17 and up to today -- 09:51

18 A. Okay. 09:51

19 Q. -- what did you do -- what have you done 09:51

20 to prepare for today's session? 09:51

21 A. What I said already. I organized my 09:51

22 papers and I reviewed the report. Preparation, if 09:51

23 that's what you want to call it, for the -- with 09:51

24 Miss Johnson and Mr. Kerensky was just a matter of 09:51

25 just show up and your organize your papers. I 09:51



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1 don't think you need to do much else. And you 09:51

2 just do what you did last time. 09:52

3 Miss Johnson didn't provide any guidance 09:52

4 whatsoever. She was in the process of looking up 09:52

5 some additional documentation, but I never looked 09:52

6 at it. 09:52

7 Q. How many times have you -- did you speak 09:52

8 with Miss Johnson between January 25th and today? 09:52

9 A. Specifically a number, I don't know. 09:52

10 Q. More than once? 09:52

11 A. Once, maybe. 09:52

12 Q. Twice? 09:52

13 A. Maybe. I don't think it was more than 09:52

14 two. 09:52

15 Q. Did you speak to her? 09:52

16 A. Yesterday, yes, for sure. 09:52

17 Q. Any time before yesterday and since 09:52

18 January 25th? 09:52

19 A. I don't recall. 09:52

20 Q. How about Mr. Kerensky? Did you speak 09:52

21 to him between January 25th and today? 09:52

22 A. Well, yesterday, coordinated to get 09:52

23 here. 09:52

24 Q. Other than yesterday, have you spoken to 09:52

25 Mr. Kerensky since January 25th? 09:52

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1 A. Perhaps once. 09:52

2 Q. When? 09:53

3 A. I don't recall specifically. 09:53

4 Q. Was that a telephone conversation? 09:53

5 A. I -- I don't recall specifically. It 09:53

6 was not what you would consider prep. It was just 09:53

7 coordination. 09:53

8 Q. Dr. Bliesner, you need to answer my 09:53

9 questions. 09:53

10 A. Uh-huh. I'm answering your questions. 09:53

11 Q. No, you're not. I asked you if you 09:53

12 spoke to Mr. Kerensky. I didn't ask you to 09:53

13 characterize the phone call yet. 09:53

14 Have you spoken to Mr. Kerensky since January 09:53

15 25th? 09:53

16 A. Yes. 09:53

17 Q. Was it a telephone conversation? 09:53

18 A. Yes. 09:53

19 Q. Have you met with Mr. Kerensky in person 09:53

20 since January 25th? 09:53

21 A. No. 09:53

22 Q. I mean we're only talking about three 09:53

23 weeks. 09:53

24 A. Yeah, I didn't. 09:53

25 Q. Okay. 09:53

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1 A. I know this was prep per se. It's not 09:53

2 like we sat down and spent hours going back and 09:53

3 forth and discussing how I'm supposed to respond 09:53

4 to your questions or anything like that. It was 09:54

5 just like are we on? Just organize your paper. 09:54

6 That stuff. Nothing detailed. 09:54

7 Q. So you didn't have any discussion with 09:54

8 Mr. Kerensky since January 25th about what 09:54

9 happened on January 25th and what you might expect 09:54

10 to happen during this session? 09:54

11 A. Between January 25th and this morning? 09:54

12 Q. Yes. 09:54

13 A. Interestingly enough, I don't think I 09:54

14 heard anything from him following the whole thing. 09:54

15 Q. Well, how many times did you speak to 09:54

16 him? 09:54

17 A. I said yesterday I know for sure. Maybe 09:54

18 one other time to coordinate the schedule and that 09:54

19 was it. 09:54

20 Q. Well, he told you to organize your 09:54

21 papers. That's not coordinating the schedule, is 09:54

22 it? 09:54

23 A. It's -- it's what he told me to do. He 09:54

24 says don't worry necessarily about preps, words to 09:54

25 that effect. Just organize your papers so you 09:54

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1 don't flounder around and waste people's time. 09:54

2 Q. And how long was your conversation with 09:55

3 Mr. Kerensky? 09:55

4 A. That particular one? 09:55

5 Q. Yeah. 09:55

6 A. Maybe a minute or two. 09:55

7 Q. Were there other conversations before 09:55

8 yesterday and since January 25th besides that 09:55

9 minute or two conversation? 09:55

10 A. There may have been one other, but it 09:55

11 was nothing extensive. 09:55

12 Q. How long was it? 09:55

13 A. If there was one, it was e-mail or 09:55

14 whatever. Similar thing. Maybe a minute and a 09:55

15 half. 09:55

16 Q. Well, was it a conversation or was it 09:55

17 e-mail communication. Because I haven't asked 09:55

18 about e-mails communications. I asked you about 09:55

19 conversations. 09:55

20 A. I don't know. I'd have to go pull them 09:55

21 out and look at them. All I know is none of these 09:55

22 conversations were substantive in terms of 09:55

23 guidance or anything like that. 09:55

24 Q. Dr. Bliesner, I am entitled to find out 09:55

25 how many there were, then we'll talk about the 09:55

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1 substance of them; okay? 09:55

2 A. I cannot tell you with certainty how 09:55

3 many telephone conversations or e-mails I had with 09:55

4 them. I know that it was not a large number. 09:55

5 Q. Okay. So you know that it was more than 09:56

6 one, though; correct? 09:56

7 A. I can't say that with certainty. I 09:56

8 really don't. My life is busy. I'm working 70, 09:56

9 80 hours a week on another consulting job. This 09:56

10 is minor in terms of coordination, get things 09:56

11 done. I don't know. I can't say it explicitly. 09:56

12 I'm not going to make stuff up to make you happy. 09:56

13 Q. I'm not asking you to make me happy. 09:56

14 I'm merely asking you to answer my questions 09:56

15 truthfully. 09:56

16 As we said earlier, you're a very intelligent 09:56

17 man and we're only talking about a three-week 09:56

18 period here. 09:56

19 MR. KERENSKY: I think I need a break. 09:56

20 MR. ANDERTON: Why do you need a break? 09:56

21 MR. KERENSKY: I have to go to the 09:56

22 bathroom. 09:56

23 MR. ANDERTON: All right. All right. 09:56

24 Let's go off the record. 09:56

25 THE VIDEOGRAPHER: The time is 09:56

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1 9:56 p.m. -- we're going -- or a.m. We're 09:56  
2 going off the record. 09:56  
3 (Short break) 10:08  
4 THE VIDEOGRAPHER: The time is . We 10:08  
5 are back on the record. This is the beginning 10:08  
6 of tape three. 10:08  
7 MR. ANDERTON: Mike, are you with us? 10:09  
8 MR. KERENSKY: I am. 10:09  
9 BY MR. ANDERTON: 10:09  
10 Q. All right. Dr. Bliesner, before 10:09  
11 Mr. Kerensky's break or requested break, we were 10:09  
12 discussing what you've done to prepare for today's 10:09  
13 session and I just want to remind you of something 10:09  
14 we agreed earlier in the day and that is that you 10:09  
15 would focus very hard on the questions that I ask 10:09  
16 and do your best to actually answer those 10:09  
17 questions. 10:09  
18 A. I understand. 10:09  
19 Q. Okay. So I'm going to go back into some 10:09  
20 of that subject. 10:09  
21 A. Okay. 10:09  
22 Q. How many times have you spoken to 10:09  
23 Mr. Kerensky on the telephone since January 25th? 10:09  
24 A. I really honestly don't know. 10:09  
25 Q. Is it more than just yesterday? 10:09

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1 A. I really honestly don't know. 10:09

2 Q. Dr. Bliesner, we're talking about a 10:09

3 three-week period and you're -- as I've said -- 10:09

4 obviously a very intelligent, very organized 10:10

5 individual. Prepared a very extensive report in 10:10

6 this case, reviewed thousands of pages of 10:10

7 documents. I'm merely asking you how many times 10:10

8 you've spoken on the telephone to Mr. Kerensky in 10:10

9 the last three weeks. 10:10

10 A. I honestly cannot tell you for sure. 10:10

11 Q. Have you spoken to any lawyers other 10:10

12 than Mr. Kerensky and Ms Johnson in the last three 10:10

13 weeks? 10:10

14 A. Yes. 10:10

15 Q. Who? 10:10

16 A. A gentleman out of Oklahoma. 10:10

17 Q. Brad Miller? 10:10

18 A. Yes. 10:10

19 Q. When did you speak to Brad Miller? 10:10

20 A. Yesterday. 10:10

21 Q. What prompted that phone conversation 10:10

22 with Mr. Miller? 10:10

23 A. Apparently he had the opportunity to 10:10

24 review my report. 10:10

25 Q. And tell me about that conversation with 10:10

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1 Mr. Miller. 10:10

2 A. He was just curious of -- my involvement 10:11  
3 in the -- in this case. 10:11

4 Q. How long did the phone conversation last 10:11  
5 with Mr. Miller, yesterday? 10:11

6 A. Maybe a half an hour. 10:11

7 Q. So what did you discuss with Mr. Miller 10:11  
8 during that 30-minute or so phone conversation? 10:11

9 A. What I did for a living primarily. 10:11

10 Q. Yeah. 10:11

11 A. And a few things about the report. 10:11

12 Q. Such as? Mike? Mike? Mike? 10:11

13 MR. KERENSKY: Yes, sorry, sorry, sorry. 10:11

14 BY MR. ANDERTON: 10:12

15 Q. A few things about the report, 10:12  
16 Dr. Bliesner. Such as what? 10:12

17 A. The conclusions that were in there. 10:12  
18 That was it primarily. 10:12

19 Q. Well tell me about that discussion with 10:12  
20 Mr. Miller about the conclusions that were in 10:12  
21 there. 10:12

22 A. Just what's written in the report. My 10:12  
23 conclusions with respect to compliance and those 10:12  
24 kinds of things. It wasn't a very specific 10:12  
25 discussion. It was more about my work background, 10:12



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1 what I'd done, what I do now, things like that. 10:12

2 Q. Well, I want to know what you discussed 10:12

3 with him with respect to the conclusion in your 10:12

4 report. Tell me about that conversation. It was 10:12

5 just yesterday. 10:12

6 A. Yes. 10:12

7 Q. So tell me about that conversation. 10:12

8 A. Basically said you have the report, the 10:12

9 conclusions that I have come to in the report are 10:12

10 supported by the documents that are in the 10:12

11 attachment. That's how I did the review. 10:12

12 Q. What kind of questions did Mr. Miller 10:12

13 ask you with respect to the conclusions in your 10:12

14 report yesterday? 10:12

15 A. I think he asked me if I reviewed any 10:13

16 additional documents since I wrote the report. 10:13

17 Q. What did you tell him? 10:13

18 A. I said additional documents, no. It was 10:13

19 just like I told you. I just prepared for this 10:13

20 and then organized them, so... 10:13

21 Q. Well, you didn't tell me that you 10:13

22 prepared for this. 10:13

23 A. Well, what I did to get ready for this 10:13

24 was organize my mass of documents after the last 10:13

25 thing so I wouldn't waste time. 10:13

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1 Q. Okay. And so he asked you what 10:13  
2 additional documents or whether you had reviewed 10:13  
3 any additional documents. You told Mr. Miller you 10:13  
4 had not reviewed any additional documents since 10:13  
5 you wrote the report? 10:13  
6 A. I'm pretty sure that's what I told him. 10:13  
7 Q. Well, let me ask you -- 10:13  
8 A. Uh-huh. 10:13  
9 Q. -- have you reviewed any additional 10:13  
10 documents since you wrote the report? 10:14  
11 A. Other than what was already present -- 10:14  
12 what I did the last time, no, I have not. 10:14  
13 Q. What do you mean by other than what you 10:14  
14 did the last time. 10:14  
15 A. This stuff. All of these documents that 10:14  
16 are in here. 10:14  
17 Q. The documents that are in there -- and 10:14  
18 so that we're clear, Dr. Bliesner, you're pointing 10:14  
19 to boxes that you brought with you; correct? 10:14  
20 A. Uh-huh. 10:14  
21 Q. Those are documents you had reviewed as 10:14  
22 you wrote the report or as you were in the process 10:14  
23 of writing the report; is that correct? 10:14  
24 A. Yes. The supporting data for this. 10:14  
25 Q. "The supporting data for this" meaning 10:14

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1 your report? 10:14

2 A. Yes. 10:14

3 Q. Are the documents in these boxes that 10:14

4 you read and reviewed after you wrote and 10:14

5 submitted the report -- the date of your report is 10:14

6 June 15, 2010. 10:14

7 A. This would be the only one. This is the 10:14

8 deposition. 10:14

9 Q. Of? 10:14

10 A. Of last time we met. It was sent to me, 10:14

11 but I need to review. I haven't gotten all the 10:15

12 way through it. 10:15

13 Q. So the transcript of January 25th? 10:15

14 A. Yes. 10:15

15 Q. Your deposition proceedings? 10:15

16 A. Yes. 10:15

17 Q. Is that the only document that you have 10:15

18 reviewed that relates to this litigation and to 10:15

19 your report since you wrote the report? 10:15

20 A. No. Because you also asked me to get 10:15

21 what my hourly rate was and the billing records. 10:15

22 Q. Okay. 10:15

23 A. So those are the things. 10:15

24 Q. Other than your billing records and the 10:15

25 transcript of the January 25th session, are there 10:15

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1 any other documents that you've reviewed that 10:15  
2 relate to this litigation and to the report issued 10:15  
3 in this litigation since June 15, 2010? 10:15

4 A. Since June 15th? 10:15

5 Q. Since you submitted your report. 10:15

6 A. Uh-huh. I can't recall if there were 10:15  
7 any specific additional documents. I don't 10:16  
8 believe there were. Because when the report was 10:16  
9 done, I was pretty much checked out and 10:16  
10 concentrating on a current client. 10:16

11 Q. When Mr. Miller asked you that question 10:16  
12 yesterday, is that what you told him as well, that 10:16  
13 you can't recall? 10:16

14 A. He didn't explicitly ask the question 10:16  
15 like you did. 10:16

16 Q. What did he ask? 10:16

17 A. He said have you reviewed any additional 10:16  
18 documentation. 10:16

19 Q. And what did you say? 10:16

20 A. I said not that I remember. 10:16

21 Q. What else did Mr. Miller ask you? 10:16

22 A. That was about it. 10:16

23 Q. Well, it was a 30-minute conversation, 10:16  
24 Dr. Bliesner. And it doesn't take 30 minutes to 10:16  
25 ask you if you reviewed additional documents and 10:16

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1 to talk about the background of the work that you 10:16  
2 do. So what else did Mr. Miller ask you yesterday 10:16  
3 when you spoke with him? 10:16

4 A. We talked about -- just to get 10:16  
5 acquainted, talked about my other two companies. 10:16

6 Q. Did you talk about your deposition 10:17  
7 today? 10:17

8 A. I did mention to him that I went through 10:17  
9 it. 10:17

10 Q. That you were? 10:17

11 A. Today's? 10:17

12 Q. Yes. 10:17

13 A. No, no. But the one before, yeah. 10:17

14 Q. Did you talk about your January 25th 10:17  
15 session with him? 10:17

16 A. A little, yes. 10:17

17 Q. What did you talk about with him with 10:17  
18 respect to the January 25th deposition session? 10:17

19 A. How difficult it was because I've never 10:17  
20 done anything like this before. 10:17

21 Q. Why do you think it's difficult? 10:17

22 A. It's just a different way of doing 10:17  
23 business than anything I've ever seen before. 10:17

24 Q. In what way? 10:17

25 A. That's a good question. 10:17

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1 Q. Every so often I try to come up with a 10:17  
2 good one. 10:17

3 A. I'm used to collaborative conversations 10:17  
4 not combative conversations. 10:17

5 Q. I don't intend for this to be a 10:18  
6 combative conversation. Do you intend for this to 10:18  
7 be a combative conversation? 10:18

8 A. Absolutely not. 10:18

9 Q. Do you think this is a combative 10:18  
10 conversation? 10:18

11 A. It's not fun. I can tell you that. 10:18

12 Q. Well, just because it's not fun doesn't 10:18  
13 mean it's combative, does it? 10:18

14 A. I suppose not. 10:18

15 Q. Do you think this is a combative 10:18  
16 conversation or a combative process? 10:18

17 MR. KERENSKY: I think you can be that 10:18  
18 way, Mike. But let's try and ask some real 10:18  
19 questions about the case. 10:18

20 BY MR. ANDERTON: 10:18

21 Q. I'm waiting for an answer, Dr. Bliesner. 10:18

22 A. I don't know if combative is the right 10:18  
23 word for it, but it's not the give and take, 10:18  
24 casual problem-solving in an open environment that 10:18  
25 I'm used to in my workplaces. 10:18

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1 Q. And were you told to make it so when you 10:19

2 prepared for your first deposition session? 10:19

3 A. Told what, sir? 10:19

4 Q. Well, I'm going to hand you -- and I 10:19

5 don't have a stapler so this isn't stapled. 10:19

6 A. Uh-huh. 10:19

7 Q. We marked this last time as -- 10:19

8 A. Yes. 10:19

9 Q. -- Exhibit 109. 10:19

10 A. Yes. 10:19

11 Q. Do you see that, Dr. Bliesner? 10:19

12 A. I do. 10:19

13 Q. Tell me what it is. Mike. Typing. 10:19

14 MR. KERENSKY: I'm sorry. 10:19

15 THE WITNESS: This is my notes of 25 10:19

16 January. Yeah, outlines a condensation of 10:19

17 points that are listed in the report, some 10:19

18 scratching with respect to calculation that we 10:20

19 were talking about. 10:20

20 BY MR. ANDERTON: 10:20

21 Q. And you actually made the body notes on 10:20

22 page 1 during your last deposition; right? 10:20

23 A. Bottom one, yes, yes. Yeah, that was 10:20

24 the thickness discussion if I recall properly. 10:20

25 Q. All right. 10:20

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1 A. Uh-huh. 10:20

2 Q. So, let's go to page 2. 10:20

3 A. Okay. 10:20

4 Q. What are those? 10:20

5 A. Guidance from Mr. Kerensky on how things 10:20

6 would go generally in a deposition because I've 10:20

7 never been in one like this, so... 10:20

8 Q. These are notes that you made -- 10:20

9 A. Uh-huh. 10:20

10 Q. -- of a conversation? You have to 10:20

11 answer yes or no, Doctor. 10:20

12 A. Oh, I'm sorry. Yes. 10:20

13 Q. Of a conversation you had with 10:20

14 Mr. Kerensky? 10:20

15 A. And Mr. Miller and the other gentleman 10:20

16 that was with them, the other attorney. 10:20

17 Q. Mr. Thompson, Fred Thompson? 10:20

18 A. No, no, no. This was the day before 10:20

19 the -- 10:21

20 MR. KERENSKY: I think it was Terry 10:21

21 Kilpatrick. 10:21

22 MR. ANDERTON: Terry Kilpatrick? 10:21

23 THE WITNESS: Yeah. 10:21

24 MR. KERENSKY: Meghan was there, too. 10:21

25 THE WITNESS: Meghan, yeah, was there 10:21



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1 too. 10:21

2 BY MR. ANDERTON: 10:21

3 Q. So there were four lawyers there: 10:21

4 Mr. Kerensky, Mr. Miller, Ms Johnson, and 10:21

5 Mr. Kilpatrick. 10:21

6 A. Yes. 10:21

7 Q. Who told you to answer questions as 10:21

8 briefly as possible, to give no more or no less 10:21

9 than is needed? 10:21

10 A. I believe that they -- all of the people 10:21

11 in that room gave that guidance if I recall. 10:21

12 Q. One of your notes here says, "saying no 10:21

13 closes the door." What does that mean? Well, 10:21

14 what does it mean? 10:21

15 A. If there is additional information that 10:21

16 needs to come out that would clarify the 10:21

17 situation, you can just go no. Then you're not 10:21

18 going to have that conversation again. So -- as I 10:21

19 understood the guidance. 10:22

20 Q. Who -- well, whose term is "closes the 10:22

21 door." Who said that to you? 10:22

22 A. I don't know which one specifically. 10:22

23 This is a whole new process for me at this stage 10:22

24 of the game so I was just listening. 10:22

25 Q. What does it mean, "keep doors open." 10:22

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1 What does that mean? 10:22

2 A. If there's line of questions that would 10:22

3 add clarification to the conversation, I want to 10:22

4 make sure that they stay open. Just saying no, it 10:22

5 stops conversation potentially in the future. 10:22

6 Q. And your notes say "yes, but" and what I 10:22

7 will call ellipses and "no, but" with another 10:22

8 ellipses. What do those notes mean? 10:22

9 A. Those are with respect to, for instance, 10:22

10 if you would ask a question that was very narrow 10:22

11 that didn't necessarily include the additional 10:22

12 information that I felt would be appropriate to 10:22

13 explain the situation, "but" let's me continue on 10:22

14 to give the additional information to clarify the 10:22

15 point. 10:23

16 Q. So you don't believe in answering -- 10:23

17 they told you not to answer a narrowly crafted 10:23

18 question with a narrow answer; is that right? 10:23

19 A. I don't think I got that specific 10:23

20 guidance. 10:23

21 Q. Well, I was merely following up on your 10:23

22 response a moment ago, Dr. Bliesner. 10:23

23 These notes are from a meeting that occurred 10:23

24 when? 10:23

25 A. That was the day before we had the first 10:23

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1 deposition. 10:23

2 Q. So January 24th. 10:23

3 A. I believe that was the date, yes. 10:23

4 Q. Did you meet with the lawyers for the 10:23

5 Plaintiffs in person to prepare for the January 10:23

6 25th deposition other than on January 24? 10:23

7 A. To prepare for the deposition? 10:23

8 Q. Yes. 10:23

9 A. No. 10:23

10 Q. Did you talk to them on the telephone, 10:23

11 any of them, to prepare for the deposition other 10:23

12 than on January 24th? 10:24

13 A. I can't recall specifically. 10:24

14 Q. You don't remember whether you even had 10:24

15 a conversation with them? 10:24

16 A. No, I don't. I have conversations with 10:24

17 people day in and day out and this is just one 10:24

18 small part of it. I can't recall. 10:24

19 Q. Well, you had to make arrangements to 10:24

20 meet with them on the 24th; correct? 10:24

21 A. Yes. 10:24

22 Q. So you had to have some communication. 10:24

23 Do you think that was by telephone? 10:24

24 A. Perhaps and perhaps e-mail. I have to 10:24

25 go back and look at them. 10:24

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1 Q. Well, would you have those e-mails with 10:24  
2 you? 10:24  
3 A. I believe I gave all of those to Miss 10:24  
4 Johnson. We copied them over off of an external 10:24  
5 hard drive and she has them. 10:25  
6 Q. She has them? 10:25  
7 A. Huh-huh. 10:25  
8 Q. Do you have them? 10:25  
9 A. No. 10:25  
10 Q. Do you have the hard drive with you? 10:25  
11 A. Yes. 10:25  
12 Q. May I see it, please? 10:25  
13 A. Sure. 10:25  
14 Q. Let's go back to your conversation 10:25  
15 yesterday with Brad Miller. 10:25  
16 A. Okay. 10:25  
17 Q. How did he come to have your contact 10:25  
18 information, do you know? 10:25  
19 A. I believe he said Pete Miller and he had 10:25  
20 interacted. I believe that's what he said. 10:25  
21 Q. Did -- did Mr. Miller -- Brad Miller, 10:25  
22 since we now have two Millers -- did Brad Miller 10:25  
23 yesterday -- did you and he discuss the 10:25  
24 possibility of him retaining you as an expert in 10:26  
25 his case? 10:26

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1 A. We did have that conversation. 10:26

2 Q. And tell me about that conversation. 10:26

3 A. He asked me, you know, whether I was 10:26  
4 interested potentially in doing it. 10:26

5 MR. KERENSKY: I need to interrupt for a 10:26  
6 second. We may be treading into a violation 10:26  
7 of the consulting expert privilege. 10:26

8 MR. ANDERTON: Well, okay. 10:26

9 MR. KERENSKY: Because I don't know if 10:26  
10 Brad hired him or not hired him. At this 10:26  
11 point, I think that would make him a 10:26  
12 consulting expert. Since I'm here not for -- 10:26  
13 I'm here for Miss Vega, but I think the 10:26  
14 witness should be advised that conversations 10:26  
15 prior to being retained by a Plaintiff's 10:26  
16 lawyer are confidential and protected and 10:26  
17 privileged under what we call the consulting 10:26  
18 expert rule. And until you're retained and 10:26  
19 disclosed as a testifying expert, those 10:26  
20 conversations are privileged. And I guess I 10:27  
21 will assert that privilege on behalf of Mr. -- 10:27  
22 is it Miller, Brad Miller? 10:27

23 THE WITNESS: Yes. 10:27

24 MR. KERENSKY: Okay. 10:27

25 MR. ANDERTON: Well, Mike, I'm not sure I 10:27

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1 agree with your characterization of the 10:27  
2 privilege and I hope that you're not making a 10:27  
3 representation of Oklahoma law with respect to 10:27  
4 expert privileges, are you? 10:27

5 MR. KERENSKY: Oh, I think it's in the 10:27  
6 federal rules, consulting experts. 10:27

7 MR. ANDERTON: Well, you are aware 10:27  
8 Mr. Kerensky of course that the case 10:27  
9 Mr. Miller is discussing with Dr. Bliesner -- 10:27  
10 with Dr. Bliesner is not a federal case; 10:27  
11 right. 10:27

12 MR. KERENSKY: Well, I'm guessing that 10:27  
13 Oklahoma law probably has the same privileges 10:27  
14 as every other state I've been in. So no 10:28  
15 doubt I'm guessing but I want to make sure 10:28  
16 that I assert the privilege to the extent it 10:28  
17 exists. During the case I'm sure you've 10:28  
18 updated yourself on the rules and know one way 10:28  
19 or the other whether it exists. And I just 10:28  
20 think I owe it to him to assert it at this 10:28  
21 time. 10:28

22 MR. ANDERTON: Okay. 10:28

23 BY MR. ANDERTON: 10:28

24 Q. Have you been retained by Brad Miller? 10:28

25 A. No. 10:28

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1 Q. Do you anticipate that you're going to 10:28

2 talk to him again? 10:28

3 A. Perhaps. 10:28

4 Q. Let's go back to what you did to 10:28

5 prepare. 10:29

6 The -- before January 25th, we know that you 10:29

7 met with Mr. Kerensky and several other folks to 10:29

8 prepare for the session the next day. How long 10:29

9 did that meeting on January 24th last? 10:29

10 A. I think last time I said it was 10:29

11 something in the neighborhood of four, five hours, 10:29

12 something like that. 10:29

13 Q. Did you -- 10:29

14 A. That I recall. 10:29

15 Q. I asked you a moment ago if you met with 10:29

16 any of those Plaintiffs' lawyers in person other 10:29

17 than on January 24th. Your testimony was no, you 10:29

18 did not; correct? 10:29

19 A. For preparation with the deposition. 10:29

20 Q. You met with them in person as you 10:29

21 prepared your report? 10:29

22 A. Yes, one time. 10:29

23 Q. Where was that? 10:30

24 A. In Indian Rocks Beach. 10:30

25 Q. They came to see you? 10:30

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1	A.	Uh-huh.	10:30
2	Q.	Yes or no?	10:30
3	A.	They came to see me. Yes. Sorry.	10:30
4	Q.	That's all right.	10:30
5	A.	Sorry.	10:30
6	Q.	I'm just trying to make sure that the.	10:30
7	A.	Yes.	10:30
8	Q.	Videographer and court reporter --	10:30
9	A.	It actually wasn't in preparation of	10:30
10		the -- well, it wasn't writing the report. They	10:30
11		just delivered more documents to me.	10:30
12	Q.	In person?	10:30
13	A.	Uh-huh.	10:30
14	Q.	That's awfully nice of them.	10:30
15	A.	Uh-huh.	10:30
16	Q.	Who did that?	10:30
17	A.	Who was there?	10:30
18	Q.	Yeah, who delivered the documents?	10:30
19	A.	It was Pete Miller and Meghan Johnson	10:30
20		Carter.	10:30
21	Q.	How long -- did you have a meeting with	10:30
22		them when they delivered more documents?	10:30
23	A.	They actually came over to my home	10:30
24		office.	10:30
25	Q.	So did you have a meeting with them?	10:30



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1 A. If you'd call it a meeting, yes. 10:30

2 Q. How long? 10:30

3 A. I honestly have to go back and look it 10:30

4 up. 10:30

5 Q. Did you bring your billing and time 10:30

6 records with you? 10:30

7 A. Yes, I did. 10:30

8 Q. May I see them? 10:30

9 A. Sure. 10:30

10 Q. Phil, you want to mark those, please? 10:31

11 Let's call it 145 please. 10:31

12 (Whereupon, Exhibit 145 was marked for 10:31

13 identification) 10:31

14 Dr. Bliesner, I'm looking at a document that 10:31

15 has been marked as Exhibit 145. 10:31

16 A. Uh-huh. 10:31

17 Q. And it is a stack of invoices that you 10:31

18 just handed me; is that correct? 10:31

19 A. I guess it is. 10:32

20 Q. Is this all of the invoices that you 10:32

21 have submitted to Plaintiffs' counsel for your 10:32

22 services as an expert witness? Dr. Bliesner, you 10:32

23 just handed -- I asked you if you had -- 10:32

24 A. Yes. 10:32

25 Q. -- your billing records. 10:32

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1           A.     I don't do the billing so I don't know           10:32  
2     if these are all of the invoices. I was looking           10:32  
3     for the last date on here.           10:32  
4           Q.     You were asked to bring them with you.           10:32  
5           A.     Yes.           10:32  
6           Q.     I just asked you if you brought them.           10:32  
7     You said yes.           10:32  
8           A.     Yes, sir.           10:32  
9           Q.     In response I said may I see them and           10:32  
10    you said yes.           10:32  
11          A.     Yes.           10:32  
12          Q.     And then you handed me a stack of           10:32  
13    documents.           10:32  
14          A.     Yes, sir.           10:32  
15          Q.     Are you now looking at them as though           10:32  
16    you're not sure whether you actually brought the           10:32  
17    right records with you? What are you doing?           10:32  
18          A.     Well, you said "all records"; okay.           10:32  
19          Q.     I said are they all of the invoices.           10:32  
20          A.     All the invoices. I Am not sure because           10:32  
21    I prepared this stack immediately after the last           10:32  
22    deposition at your request. I'm not sure whether           10:32  
23    that deposition invoice was included in this           10:33  
24    stack. See what I'm saying?           10:33  
25          Q.     Okay.           10:33

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1 A. That's all I'm trying to do. 10:33

2 Q. You were asked to bring them with you 10:33

3 today. Did you not double check to make sure you 10:33

4 had all the records you were supposed to bring? 10:33

5 A. I forwarded them via e-mail to 10:33

6 Mr. Miller and Mr. -- Miss Johnson before. So I 10:33

7 made the assumption that they forwarded them to 10:33

8 you. 10:33

9 Q. They did not. 10:33

10 A. Okay 10:33

11 Q. And you know that you were asked to 10:33

12 bring them with you today; right? 10:33

13 A. Yes, yes. 10:33

14 Q. So -- 10:33

15 A. I brought a copy because I thought that 10:33

16 you got them all. 10:33

17 Q. I have got nothing. 10:33

18 A. Okay. 10:33

19 Q. From any of the lawyers and Plaintiffs. 10:33

20 A. Okay. 10:33

21 Q. Or any of the Plaintiffs' lawyers. 10:33

22 A. Okay. 10:33

23 Q. That's why we asked you to bring them. 10:33

24 A. Okay. 10:33

25 Q. You understood that you were supposed to 10:33

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1 bring all of your billing records today; correct? 10:33

2 A. Not specifically because I'd already 10:33

3 provided them. I just brought this because this 10:33

4 is the hard copy that I had I scanned in e-mail, 10:33

5 so... 10:34

6 Q. When did you provide them to Plaintiffs' 10:34

7 counsel? After January 25th? 10:34

8 A. Yes. At your request. 10:34

9 Q. Okay. I guess then you have to look 10:34

10 through that stack of documents and take up more 10:34

11 of our time looking at something that you should 10:34

12 know because you should have been prepared to 10:34

13 bring them with you today, but if you need to, 10:34

14 please do. 10:34

15 MR. KERENSKY: Objection, form. 10:34

16 MR. ANDERTON: Proceed, Dr. Bliesner. 10:34

17 THE WITNESS: This does not include last, 10:35

18 the 25th's billing. 10:35

19 BY MR. ANDERTON: 10:35

20 Q. Have you invoiced Plaintiffs' counsel 10:35

21 for that -- for the time that you spent preparing 10:35

22 for and participating in the January 25th 10:35

23 deposition? 10:35

24 A. I don't know because I don't do it. 10:35

25 Q. Dr. Bliesner, I see -- did you review 10:35

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1 these documents before you came here today? 10:35

2 A. That stack? 10:35

3 Q. Yes. 10:35

4 A. No. 10:35

5 Q. The first invoice indicates a rate of 10:35

6 \$350. It's dated January 16, 2010, \$350 per 10:35

7 hour. And the next invoice dated a week later, 10:35

8 January 23rd, indicates a rate of \$550 per hour. 10:35

9 Did your rate go up? 10:35

10 A. There was a misunderstanding on the rate 10:35

11 to begin with. 10:36

12 Q. Whose misunderstanding? 10:36

13 A. The Miller Law Firm. 10:36

14 Q. You sent the invoice out. 10:36

15 A. Yes. 10:36

16 Q. So whose misunderstanding? 10:36

17 A. This was the additional -- I thought 10:36

18 that you received that as well but apparently not. 10:36

19 Q. As I've said, I've not received anything 10:36

20 from Plaintiffs about -- 10:36

21 A. Uh-huh. 10:36

22 Q. -- your communications with them -- 10:36

23 A. Uh-huh. 10:36

24 Q. -- your billing records -- 10:36

25 A. Uh-huh. 10:36

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1 Q. -- anything. 10:36

2 A. Uh-huh. 10:36

3 Q. So you just handed me a document that 10:36

4 Phil is going to mark as Exhibit 146. 10:36

5 A. Uh-huh. 10:36

6 Q. Please, Phil. Thank you, sir. 10:36

7 A. And this was prior to being retained 10:37

8 obviously. 10:37

9 Q. Prior to being retained. 10:37

10 A. Yes. 10:37

11 (Whereupon, Exhibit 146 was marked for 10:37

12 identification) 10:37

13 Q. So I'm reading a letter that says -- 10:37

14 well, tell me what this is, 146. Is it an e-mail, 10:37

15 is it a letter, what is it? 10:37

16 A. This is -- I believe it is a Word 10:37

17 document that I cut and paste into e-mail. So I 10:37

18 can -- I design a document first. 10:37

19 Q. Okay. 10:37

20 A. And I put it in an e-mail. So this is 10:37

21 what that is. 10:37

22 Q. That's just a Word document? 10:37

23 A. I'm thinking it is. 10:37

24 Q. You're thinking it is? 10:37

25 A. Yeah. I'm not sure; okay? Because it 10:37

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1 doesn't have the headers on it or not so I can't 10:37  
2 say definitively. On something like this normally 10:37  
3 for a business transaction -- because I would like 10:37  
4 to be accurate in an e-mail -- I create a Word 10:37  
5 document first, do spell check and everything else 10:37  
6 and I cut and paste it in an e-mail. 10:37  
7 Q. So you copy the text? 10:38  
8 A. Yes. 10:38  
9 Q. And paste it into an e-mail? 10:38  
10 A. Yes, sir. 10:38  
11 Q. So that means that -- well, did you send 10:38  
12 this -- the contents of the document that is 10:38  
13 marked as 146 to Mr. Miller? 10:38  
14 A. I did. 10:38  
15 Q. In what form? 10:38  
16 A. In e-mail. 10:38  
17 Q. Do you have that e-mail with you? 10:38  
18 A. I do not. 10:38  
19 Q. Why not? 10:38  
20 A. Because I gave all the e-mails to Miss 10:38  
21 Johnson Carter. 10:38  
22 Q. May I see that, please? 10:38  
23 A. Sure. 10:38  
24 Q. So you sent an e-mail to Mr. Miller 10:38  
25 somewhere around January 4, 2010, with the 10:38

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1 following text or that includes the following 10:38  
2 text. As discussed, my rates are, and then you 10:38  
3 list your rates. 10:38  
4 A. Uh-huh. 10:38  
5 Q. \$350 an hour for standard document 10:38  
6 review, on-site time, consultations, etc. 10:38  
7 A. Uh-huh. 10:38  
8 Q. \$450 an hour for testimonies or 10:38  
9 depositions? 10:38  
10 A. Uh-huh. 10:39  
11 Q. Is that right? Is that correct? 10:39  
12 A. Is that what it says there? Yes. 10:39  
13 Q. And \$550 involving for any cases 10:39  
14 involving capital crimes. 10:39  
15 A. Uh-huh. 10:39  
16 Q. You have to say yes or no. 10:39  
17 A. Yes, sorry. 10:39  
18 Q. That's all right. 10:39  
19 A. I'll get this some day. 10:39  
20 Q. So the first invoice you submitted was 10:39  
21 at the \$350 per hour rate? 10:39  
22 A. Yes. 10:39  
23 Q. And every invoice thereafter was at the 10:39  
24 \$550 per hour rate. 10:39  
25 A. Yes. 10:39



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1 Q. Does this case involve a capital crime? 10:39

2 A. Well, it involved a death potentially. 10:39

3 So that wasn't necessarily explained to me when I 10:39

4 was doing the initial consultation. 10:39

5 Q. So you quoted your rate as \$550 per hour 10:39

6 for a case involving a capital crime? 10:39

7 A. A death, potentially. A capital crime, 10:39

8 I don't know the legal term. So that's the term I 10:39

9 used. 10:39

10 Q. Oh, you used capital crime to indicate a 10:39

11 death? 10:39

12 A. Anything that involved potentially a 10:39

13 death, yes. I'm not a lawyer. It's just a term 10:39

14 that I came up with. 10:39

15 Q. Had you ever been involved -- you've 10:39

16 never been an expert witness before. 10:40

17 A. No, absolutely not. This is all brand 10:40

18 new stuff for me. So there was confusion on that 10:40

19 and it turns out that there was potentially 10:40

20 somebody that was hurt, so the rate was increased 10:40

21 to 550. 10:40

22 Q. You misunderstood that there was 10:40

23 potentially somebody who was hurt? 10:40

24 A. It was never specifically told to me 10:40

25 that, you know, it was put to me we've got a case 10:40

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1 going on, something like this. I do have a 10:40  
2 question, though, you know? This is falling into 10:40  
3 pre, you know, retainer and stuff like that. Do I 10:40  
4 have the same right not to discuss the details 10:40  
5 here? 10:40

6 MR. ANDERTON: Well, Mr. Kerensky -- like 10:40  
7 I said, I disagree with Mr. Kerensky's 10:40  
8 characterization of the scope of that 10:40  
9 privilege. 10:40

10 THE WITNESS: Right. 10:40

11 MR. ANDERTON: So... 10:40

12 THE WITNESS: I'm not particularly 10:40  
13 comfortable talking about negotiations that I 10:40  
14 had with somebody prior to being put on 10:40  
15 retainer. 10:40

16 MR. ANDERTON: I mean no disrespect, 10:40  
17 Dr. Bliesner. Whether you're comfortable or 10:40  
18 not, it's something I'm allowed to inquire 10:40  
19 into. 10:40

20 MR. KERENSKY: Wait a minute. We're 10:40  
21 talking about -- I lost track of you guys. 10:41  
22 You're not talking back again about another 10:41  
23 case other than -- 10:41

24 MR. ANDERTON: No, no. We're talking 10:41  
25 about his retention. 10:41

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1 THE WITNESS: Prior to the retention. 10:41

2 BY MR. ANDERTON: 10:41

3 Q. You have now been disclosed -- 10:41

4 A. Uh-huh. 10:41

5 Q. -- as a testifying expert. 10:41

6 A. Uh-huh. 10:41

7 Q. So even if Mr. Kerensky's 10:41

8 characterization of the privilege is accurate, all 10:41

9 communications you've had with counsel for 10:41

10 Plaintiffs are open to my examination. 10:41

11 A. Okay. 10:41

12 Q. Okay. 10:41

13 A. Okay. 10:41

14 MR. KERENSKY: If it is about cases that 10:41

15 you've been retained, if there is a file you 10:41

16 have been retained on, he's right. Everything 10:41

17 you talked to the PSC about or anything like 10:41

18 that, that's fair game. 10:41

19 MR. ANDERTON: And that's what we're 10:41

20 discussing, Mike. You'll see when you see 10:41

21 Exhibit 146 that it is communication between 10:41

22 Dr. Bliesner and Pete Miller. 10:41

23 MR. KERENSKY: Okay. That's great. 10:41

24 THE WITNESS: Okay. 10:41

25 BY MR. ANDERTON: 10:41

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1 Q. So -- and why aren't you comfortable 10:41

2 discussing negotiations you had? 10:41

3 A. It's just bad business to talk to other 10:41

4 people about negotiations in business with your 10:42

5 clients. 10:42

6 Q. Well, this isn't business, 10:42

7 Dr. Bliesner. This is testimony in a legal 10:42

8 proceeding. You understand that; right? 10:42

9 A. I agree of course, but it's a 10:42

10 transaction. 10:42

11 Q. Dr. Bliesner, did you receive a notice 10:42

12 of today's proceeding? 10:42

13 A. Today's proceeding? 10:42

14 Q. Yes. 10:42

15 A. I received a notice for the one on the 10:42

16 25th, but one specifically for today? 10:42

17 Q. Yeah. 10:42

18 A. Not that I recall. 10:42

19 Q. Not that you recall. 10:42

20 Did you look at the one that you received 10:42

21 prior to coming on January 25th? 10:42

22 A. For today? 10:43

23 Q. No, before you came on January 25th. 10:43

24 A. Yes. 10:43

25 Q. And did you review that notice to 10:43

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1 identify documents and other materials that you 10:43  
2 were supposed to bring with you on January 25th? 10:43  
3 A. For the 25th one? 10:43  
4 Q. Yes. 10:43  
5 A. Yeah. 10:43  
6 Q. One second, getting a drink. 10:43  
7 A. May I do the same? 10:43  
8 Q. Uh-huh, yes you may. Yes, you may. 10:43  
9 We'll stay on the record. 10:43  
10 Are you ready? 10:43  
11 A. Yes, sir. 10:44  
12 Q. So Dr. Bliesner, you did not receive any 10:44  
13 notice of today's deposition? 10:44  
14 A. Not that I recall, no. 10:44  
15 Q. Before you came on January 25th -- 10:44  
16 A. Uh-huh. 10:44  
17 Q. -- to the first session of your 10:44  
18 deposition, did you review the notice that you 10:44  
19 received for the 25th and collect all of the 10:44  
20 information, documents, and materials that were 10:44  
21 identified in the notice to bring with you? 10:44  
22 A. I did. 10:44  
23 Q. And did you bring them with you on that 10:44  
24 day? 10:44  
25 A. I did. 10:44

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1 Q. Did you bring them with you again today? 10:44

2 A. I did. 10:44

3 Q. Same materials? 10:44

4 A. Yes. 10:44

5 Q. Is there anything that you brought with 10:44

6 you on the 25th that isn't here today? 10:44

7 A. No. 10:44

8 Q. You went through and organized them per 10:44

9 the -- 10:44

10 A. Uh-huh. 10:44

11 Q. -- suggestion of Mr. Kerensky? 10:44

12 A. Uh-huh. 10:44

13 Q. But you brought the same materials with 10:44

14 you? 10:44

15 A. Uh-huh. 10:44

16 Q. I'll represent to you, Dr. Bliesner, 10:44

17 that this notice is identical to the prior notice 10:44

18 except for the date and time. Mr. Kerensky will 10:44

19 speak up and tell me if I'm wrong. But item 10:45

20 number 2 -- 10:45

21 A. Uh-huh. 10:45

22 Q. -- requests that you bring all 10:45

23 correspondence and communication between the 10:45

24 witness -- that's you -- and anyone acting on the 10:45

25 witness's behalf. So anyone acting on your 10:45

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1     behalf. 10:45

2           A.     Uh-huh. 10:45

3           Q.     And attorneys representing the 10:45

4     Plaintiffs in this litigation. 10:45

5           A.     Uh-huh. 10:45

6           Q.     Do you understand that request? 10:45

7           A.     Yes. 10:45

8           Q.     Did you bring those materials with you? 10:45

9     Do you have all correspondence and communication 10:45

10    between yourself or your wife as a -- 10:45

11          A.     Uh-huh. 10:45

12          Q.     -- representative of Delphi? 10:45

13          A.     Uh-huh. 10:45

14          Q.     Or -- these invoices are under Delphi. 10:45

15    Do you have all correspondence between you, your 10:45

16    wife, or anyone at Delphi and any of the 10:45

17    Plaintiffs' lawyers with you today? 10:45

18          A.     The original e-mails were copied off the 10:45

19    hard drive and Miss Johnson has them. So to 10:46

20    answer your question, that set of e-mails I do not 10:46

21    have with me. It's not on the hard drive. 10:46

22          Q.     Not on the hard drive? 10:46

23          A.     I have e-mails since that time that the 10:46

24    communications are on that hard drive. 10:46

25          Q.     So the original e-mails were copied off 10:46

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1 of that same hard drive that you brought with you 10:46  
2 today? 10:46  
3 A. Yes, sir. 10:46  
4 Q. Given -- printed off of that? 10:46  
5 A. No, they were just copied as file. 10:46  
6 Q. When did that happen? 10:46  
7 A. The 24th, I believe. That was the day 10:46  
8 before. 10:46  
9 Q. So you brought them on that same hard 10:46  
10 drive on January 24th to your meeting with 10:46  
11 Plaintiffs' counsel? 10:46  
12 A. Yes. 10:46  
13 Q. And in that meeting, somebody copied 10:46  
14 them off of that hard drive onto some media that 10:46  
15 they brought with them? 10:46  
16 A. Yes. 10:46  
17 Q. Who was that? 10:46  
18 A. It was Miss Johnson. 10:46  
19 Q. What was the media she copied it onto, 10:46  
20 do you know? 10:46  
21 A. I don't recall. 10:46  
22 Q. And then after that meeting -- 10:46  
23 A. Uh-huh. 10:47  
24 Q. -- did you bring that -- did you have 10:47  
25 that hard drive with you on the 25th? 10:47



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1 A. Yes. 10:47

2 Q. Were the e-mails between you and 10:47

3 Plaintiffs' counsel still on the hard drive at 10:47

4 that time? 10:47

5 A. No. 10:47

6 Q. So you went home on the 24th and you 10:47

7 removed them? 10:47

8 A. No, no. She copied them off. 10:47

9 Q. Well, when you copy, you don't remove. 10:47

10 A. She removed them. She copied -- cut the 10:47

11 whole folder and dropped it over onto her 10:47

12 computer. 10:47

13 Q. So you had that hard drive with you on 10:47

14 the 25th but you didn't have the e-mails with you. 10:47

15 A. No, she he did. 10:47

16 Q. She did? 10:47

17 A. Yeah. 10:47

18 MR. ANDERTON: You see that we have a 10:47

19 problem here, Mr. Kerensky? Mike? 10:47

20 MR. KERENSKY: Sorry, I was on mute. I 10:47

21 don't think -- I'm pretty sure Meghan sent 10:47

22 those to me and I was supposed to bring them. 10:47

23 I am looking for an e-mail. Why don't you 10:47

24 move to another subject and I'll see if I can 10:47

25 solve it in a minute. 10:47

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1 BY MR. ANDERTON: 10:47

2 Q. Okay. So back to -- well, I'm going to 10:48

3 stay on this subject for a minute. She copied 10:48

4 them onto some media that she had. 10:48

5 A. Yeah, I believe it was her computer. 10:48

6 Q. Okay. 10:48

7 A. That she was going to share with 10:48

8 everybody. 10:48

9 Q. And then you removed them from your hard 10:48

10 drive? 10:48

11 A. No, no, no. She took them off. 10:48

12 Everything that I've done with respect to 10:48

13 electronic records and everything else, 10:48

14 communication, has been on that external hard 10:48

15 drive. 10:48

16 Q. This one you brought you? 10:48

17 A. This exact reason. It could be shared 10:48

18 with people. 10:48

19 Q. Okay. 10:48

20 A. So when we met on the 24th. 10:48

21 Q. Correct. 10:48

22 A. Right? They said so do you have any 10:48

23 e-mails? And I said yeah, I did what you told. 10:48

24 Here they are on the external hard drive and Miss 10:48

25 Johnson plugged it in I believe it was her 10:48

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1 computer, and she goes -- there's e-mail and 10:48  
2 communications back and forth here. You got to 10:48  
3 figure out -- words to this effect, you know -- a 10:48  
4 good way to distribute them so we're not passing 10:48  
5 the hard drive around. She goes so I'm going to 10:48  
6 cut them off and then I'll make sure they're 10:48  
7 available to people. 10:49  
8 Q. Okay. She removed them from your hard 10:49  
9 drive. 10:49  
10 A. Yes. 10:49  
11 Q. And you don't have them here today. 10:49  
12 A. No. You have e-mails since that time of 10:49  
13 communication. 10:49  
14 Q. On this hard drive. 10:49  
15 A. Yes. 10:49  
16 Q. All e-mails, all correspondence between 10:49  
17 you and Plaintiffs' counsel? 10:49  
18 A. There should be, yes. I'm pretty 10:49  
19 meticulous about when I get that, I make sure it 10:49  
20 goes onto the hard drive. 10:49  
21 Q. So you're pretty meticulous that you 10:49  
22 preserve and maintain a complete set of records? 10:49  
23 A. Yes. 10:49  
24 Q. The documents that Mr. Miller and Ms 10:49  
25 Johnson delivered in person to you at your home, 10:49

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1 what were they? 10:49

2 A. I could show you. 10:49

3 Q. Please do. 10:50

4 A. We're talking just about that visit at 10:50

5 the home office. 10:50

6 Q. Well, were there other visits where they 10:50

7 delivered documents to you? 10:50

8 A. No. 10:50

9 Q. Just one? 10:50

10 A. Yes. 10:50

11 Q. Okay. Is that it? 10:50

12 A. The first set, they did not deliver. I 10:51

13 apologize for that. 10:51

14 Q. The first set? 10:51

15 A. That's stuff I had mailed to me 10:51

16 originally. 10:51

17 Q. Okay. 10:51

18 A. So on that particular day, it would have 10:51

19 been the second set I'm pretty sure. 10:51

20 Q. These two binders labeled second set? 10:51

21 A. Yeah. There may have been some 10:51

22 additional documents mailed to me prior to that 10:51

23 day, but they're all in here. 10:51

24 Q. All right. You can sit back down. 10:52

25 A. Sure. 10:52

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1 Q. That's all right. 10:52

2 A. Uh-huh. 10:52

3 Q. The other documents -- well, are there 10:52

4 other documents that you have received from 10:52

5 Plaintiffs' counsel as part of your engagement? 10:52

6 A. I've reviewed through this Crivella West 10:52

7 site. 10:52

8 Q. Okay. 10:52

9 A. Some of which I printed out to review, 10:52

10 others which I just left online because they were 10:52

11 too big. 10:52

12 Q. Okay. Are these the only documents that 10:52

13 you've actually received from Plaintiffs' counsel? 10:52

14 A. No. 10:52

15 Q. What else have you received from 10:53

16 Plaintiffs' counsel? 10:53

17 A. Yesterday evening, late, I believe I got 10:53

18 one or two reports from process development or 10:53

19 something like that. I didn't review them. 10:53

20 Q. Process validation? 10:53

21 A. I'm trying -- I don't recall because I 10:53

22 didn't look at them. 10:53

23 Q. Okay. 10:53

24 A. I got a document. I know that and I 10:53

25 just didn't look at it. 10:53

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1 Q. Who did you get that from? 10:53

2 A. Miss Johnson. 10:53

3 Q. Yesterday? 10:53

4 A. Evening, yes. 10:53

5 Q. Mail? Electronic? How did you get it? 10:53

6 A. It was electronic. 10:53

7 Q. By e-mail? 10:53

8 A. Yes. 10:53

9 Q. Is the e-mail -- 10:53

10 A. Should be on there, yes. 10:53

11 Q. Is that on the hard drive? 10:53

12 A. Yeah, should be there. 10:53

13 Q. The -- other than the documents you 10:53

14 received yesterday electronically from 10:53

15 Ms. Johnson, are there any other documents in 10:53

16 addition to the ones that you've handed me today 10:53

17 that you actually received from Plaintiffs' 10:53

18 counsel? 10:53

19 A. Not that I recall. I think this is 10:53

20 pretty much it, yeah. It's a lot of stuff so to 10:53

21 say definitively everything I've got is here. 10:53

22 Q. You just said you're a pretty meticulous 10:54

23 -- 10:54

24 A. Right. 10:54

25 Q. -- detailed guy. 10:54

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1 A. Right, right. 10:54

2 Q. That's the military background; right? 10:54

3 A. Or just anal retentiveness as a human 10:54

4 being. 10:54

5 Q. Okay. 10:54

6 A. The reason I'm not saying absolutely 10:54

7 yes, this is it, is that I'd have to go back and 10:54

8 look at the electronic records to make sure that 10:54

9 there was one attached that I didn't review or I 10:54

10 forgot about that would be there. 10:54

11 Q. But those would be included among e-mail 10:54

12 communications? 10:54

13 A. Yes. 10:54

14 Q. That Miss Johnson -- 10:54

15 A. Yes. 10:54

16 Q. -- took from you and hasn't produced to 10:54

17 us. 10:54

18 A. If she hasn't produced them, yes. 10:54

19 Q. Okay. Are there any other documents at 10:54

20 your home that you did not bring with you today 10:54

21 that you have received from Plaintiffs' counsel? 10:54

22 A. No. 10:54

23 MR. ANDERTON: Phil, we're going to mark 10:54

24 these. There are four of them. We're marking 10:54

25 documents Mike. Just show you know, there's a 10:55

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1 stack and three binders. We'll make 10:55  
2 arrangements to get them copied and back to 10:55  
3 Dr. Bliesner. 10:55  
4 MR. KERENSKY: No problem. Who is going 10:55  
5 to do the copying? 10:55  
6 MR. ANDERTON: We will figure that out 10:55  
7 before we leave today. 10:55  
8 MR. KERENSKY: Very good. 10:55  
9 THE WITNESS: Now, there are an 10:55  
10 additional documents that support the report, 10:55  
11 the attachments. 10:55  
12 (Whereupon, Exhibits 147, 148, 149, 10:55  
13 150 were marked for identification) 10:55  
14 BY MR. ANDERTON: 10:55  
15 Q. Uh-huh. 10:55  
16 A. Do you want those as well? 10:55  
17 Q. Well, we'll get there. 10:55  
18 A. Okay. 10:55  
19 Q. I take it those are documents that you 10:55  
20 reviewed and printed from the Crivella West? 10:55  
21 A. They could have been provided at some 10:55  
22 point through this document delivery that you've 10:56  
23 talked about. They e-mailed me some, they mailed 10:56  
24 me some, and then they delivered some personally. 10:56  
25 So they're all weaved together. 10:56



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1 Q. But I asked you, Dr. Bliesner, if there 10:56  
2 are any other documents that you've received from 10:56  
3 Plaintiffs' counsel. I didn't specify personal 10:56  
4 delivery. 10:56

5 A. Well. 10:56

6 Q. That's what you gave me when you gave me 10:56  
7 these things. 10:56

8 A. I'm sorry. I misunderstood you because 10:56  
9 I thought you said just for that visit at the home 10:56  
10 office. I'm sorry. 10:56

11 Q. Okay. 10:56

12 A. Uh-huh. 10:56

13 Q. So let's make sure. 10:56

14 A. Okay. 10:56

15 Q. It's imperative -- 10:56

16 A. Uh-huh. 10:56

17 Q. -- Dr. Bliesner that you listen very 10:56  
18 carefully to the questions that I ask. 10:56

19 A. I understand. 10:56

20 Q. Are there any other documents that you 10:56  
21 have received from Plaintiffs' counsel -- 10:56

22 A. Uh-huh, yes. Sorry. 10:56

23 Q. -- that you have with you today? 10:56

24 A. Yes. 10:56

25 Q. We're going to mark them. You've handed 10:56

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1 me two more binders. 10:57

2 A. Yes, sir. 10:57

3 Q. They have post-it notes on the key 10:57

4 documents A1 to A30 and A31 to A63? 10:57

5 A. Yes, sir. 10:57

6 Q. Who designated them key documents? 10:57

7 A. Me. 10:57

8 Q. Okay. I've got another stack of 10:57

9 documents with a post it on it that says last 10:58

10 supplemental set; right? 10:58

11 A. Yes. 10:58

12 Q. What is that? 10:58

13 A. Those were -- if I recall those were 10:58

14 printouts of e-mails that I received from one of 10:58

15 the attorneys prior to the 25th. 10:58

16 Q. Okay. 10:58

17 A. I believe that we reviewed those. You 10:58

18 have them as well and we've reviewed them. 10:58

19 Q. Okay. 10:58

20 A. Uh-huh. 10:58

21 Q. So these appear to be all or largely the 10:58

22 records relating to the FDA 484 sampling program. 10:58

23 You can stay right there. 10:58

24 A. Okay. It looks like there's an 10:58

25 additional set there too. So to answer your 10:59

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1 question, it appears to be that and some more. 10:59

2 Q. Okay. But you received those prior 10:59

3 to -- somewhat close in proximity to the last 10:59

4 deposition session. 10:59

5 A. Yeah. 10:59

6 Q. As I look at these binders that have 10:59

7 been marked as 148, 149 and 150. 10:59

8 A. Uh-huh. 10:59

9 Q. I see highlighting on various 10:59

10 documents. Who did the highlighting? 10:59

11 A. Let's see. 10:59

12 Q. In particular, I'm looking at -- 10:59

13 A. Oh. 10:59

14 Q. -- the third set of supplemental 10:59

15 documents. 10:59

16 Who did the highlighting? 10:59

17 A. Me. 10:59

18 Q. Is it true that any highlighting that I 10:59

19 will encounter on these documents was done by you? 10:59

20 A. I believe so, yes. 10:59

21 Q. Okay. 10:59

22 A. I -- nobody pointed out anything 10:59

23 specifically for me to... 11:00

24 Q. You can have that stack back and you can 11:00

25 put it away. 11:00

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1 A. Okay. 11:00

2 Q. We're not going to copy that or mark 11:00

3 it. 11:00

4 A. Okay. 11:00

5 Q. Now, you've handed me another binder of 11:00

6 deposition transcripts. 11:00

7 A. Yeah. Those were printed out off of 11:00

8 Crivella. 11:00

9 Q. You can have that back. We're not going 11:00

10 to mark that. 11:00

11 A. Okay. 11:00

12 Q. Are there any other documents, 11:00

13 Dr. Bliesner, that you have received from 11:01

14 Plaintiffs' counsel that you brought with you 11:01

15 today? 11:01

16 A. Other than the electronic ones that I 11:01

17 could not account for, not to my knowledge, no. 11:01

18 Q. Okay. 11:01

19 A. Uh-huh. 11:01

20 Q. What else is in the boxes that you 11:01

21 brought with you today? 11:01

22 A. Today? 11:01

23 Q. Just describe it. 11:01

24 A. Describe it? Textbook, the transcript 11:01

25 of the last deposition that I need to review. 11:01

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1 Q. What else? 11:01

2 A. I think I've got some notes from -- the 11:01

3 stuff like this. 11:01

4 Q. Some notes like that or -- 11:01

5 A. Would you like me to look? 11:01

6 Q. Sure. 11:01

7 A. Because I'm not sure whether you have 11:01

8 copies of this or not. 11:01

9 Q. Well, let me see the notes. 11:01

10 A. Sure. That's it. Did you want to -- 11:01

11 Q. No. 11:01

12 A. Okay. 11:01

13 MR. ANDERTON: While -- Phil, while we're 11:02

14 at it, we may as well mark the notice. Mike, 11:02

15 I'm marking the notice as 151. 11:02

16 (Whereupon, Exhibit 151 was marked 11:02

17 for identification) 11:02

18 BY MR. ANDERTON: 11:02

19 Q. Do you have any other notes with you? 11:02

20 A. No. 11:02

21 Q. Okay. You described -- you said you had 11:02

22 your textbook, you said you had your deposition 11:02

23 transcript, you said you had these additional 11:03

24 notes that we're about to mark. 11:03

25 A. Uh-huh. 11:03

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1 Q. Do you have anything else with you in 11:03  
2 the boxes that you brought today? 11:03

3 A. No. 11:03

4 MR. ANDERTON: Phil, would you mark these 11:03  
5 as 152 and 3? Mike, these are additional sets 11:03  
6 of notes. 11:03

7 (Whereupon, Exhibits 152 and 153 11:03  
8 were marked for identification) 11:03

9 THE VIDEOGRAPHER: The time is 11:03  
10 a.m. We're going off the record. 11:03

11 (Short break) 11:14

12 THE VIDEOGRAPHER: The time is 11:14  
13 11:14 a.m. We're back on the record. This is 11:15  
14 the beginning of tape four. 11:15

15 BY MR. ANDERTON: 11:15

16 Q. Dr. Bliesner, I'm going to hand you a 11:15  
17 document that has been marked as Exhibit 152. 11:15

18 A. Yes. 11:15

19 Q. Tell me what that is. 11:15

20 A. That's my handwritten notes I believe it 11:15  
21 was for the day when I met before the first 11:15  
22 deposition with the attorneys. 11:15

23 Q. Your handwritten notes. Okay. Well, we 11:15  
24 had some testimony earlier about a document that's 11:15  
25 marked as 109. 11:15

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1 A. Yes. 11:15

2 Q. Do you remember that? 11:15

3 A. Yes, uh-huh. 11:15

4 Q. You described those as your handwritten 11:16

5 notes. Did you take two sets of notes that day? 11:16

6 A. I cleaned them up so I could read them. 11:16

7 Q. When did you do that? 11:16

8 A. I don't recall, but I think it was at 11:16

9 the same time, like at the end of the day. 11:16

10 Q. Okay. So the document that is 109, is 11:16

11 that the uncleaned up version or is it the cleaned 11:16

12 up version? 11:16

13 A. This one right here? 11:16

14 Q. 109. 11:16

15 A. Yeah, I think that's just the summary at 11:16

16 the end of the -- this and the other notes that 11:16

17 were there. 11:16

18 Q. So the document that's 152 -- 11:16

19 A. Uh-huh. 11:16

20 Q. -- let's get them both in front you. 11:16

21 A. Okay. 11:16

22 Q. I'm also handling you a document that is 11:16

23 marked 153. 11:16

24 A. Uh-huh. 11:16

25 Q. What is that? 11:16

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1 A. 153 looks like notes from a conversation 11:16  
2 I had. 11:16  
3 Q. With? 11:16  
4 A. It looks like -- specifically, I'm not 11:16  
5 sure who called me. It was either Pete or Meghan 11:17  
6 to tell me a time. 11:17  
7 Q. To tell you a time? 11:17  
8 A. Yeah, hold on. That's not right. 10 -- 11:17  
9 oh, I'd have to look at the calendar. We did our 11:17  
10 deposition on what day of the week? 11:17  
11 Q. Tuesday. 11:17  
12 A. Tuesday, yes. So this was notes with 11:17  
13 respect to them, to meet me on the Monday before. 11:17  
14 Q. And by "this," you mean Exhibit 153? 11:17  
15 A. Yes. 11:17  
16 Q. But this is notes of a phone 11:17  
17 conversation that obviously occurred before Monday 11:17  
18 24th; right? 11:17  
19 A. I suppose that's -- that's the case, 11:17  
20 yes. 11:17  
21 Q. You suppose? 11:17  
22 A. It doesn't have a date on it. I don't 11:17  
23 have a time so I can't tell you definitively what 11:17  
24 day. 11:17  
25 Q. Are these notes that you took during 11:17



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1 that meeting with the lawyers? 11:18

2 A. No. 11:18

3 Q. And it references a meeting time and 11:18

4 place, 10 a.m., 10, Monday, 100 North Tampa. 11:18

5 A. Right. So chances are it's the 11:18

6 telephone record. 11:18

7 Q. You mean record of notes during a 11:18

8 telephone conversation? 11:18

9 A. When they called up and said, you know, 11:18

10 we want to get together on the 24th, the day 11:18

11 before. 11:18

12 Q. Well, this is a lot more than we want to 11:18

13 get together on 24th, isn't it, Dr. Bliesner? 11:18

14 A. This sheet is. The rest of them, I'm 11:18

15 not sure where -- if that was part of the day 11:18

16 that -- on the day before the deposition or not. 11:18

17 I -- I really -- because I don't have a date and a 11:18

18 time on it here. Just -- I think that this -- 11:18

19 this page 2 here of 153. 11:18

20 Q. Yeah. 11:18

21 A. If I had to offer a suggestion, I think 11:18

22 that those pages probably went with this, the 11:18

23 preparation day. 11:19

24 Q. So you think these are notes that you 11:19

25 made when you met with them on the 24th? 11:19

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1 A. Yes. 11:19

2 Q. And you think 152 are notes that you 11:19

3 made when you met with them on the 24th? 11:19

4 A. 152. 11:19

5 Q. Yes. 11:19

6 A. Yes. 11:19

7 Q. And you think that 109 is a clean up of 11:19

8 notes you made when you met with them on the 24th 11:19

9 and made them later that day? 11:19

10 A. Yes. 11:19

11 Q. Three sets of notes, Dr. Bliesner. 11:19

12 Really? 11:19

13 A. Three set pages. 11:19

14 Q. In the same day? 11:19

15 A. This is the telephone conversation. 11:19

16 Q. The first page of Exhibit 153. 11:19

17 A. 153. 11:19

18 Q. Your testimony is that what remains in 11:19

19 153 -- and just so we're clear -- 11:19

20 A. Uh-huh. 11:19

21 Q. -- you handed me the document that we've 11:19

22 marked as Exhibit 153 -- 11:19

23 A. Yes. 11:19

24 Q. -- as a single group of notes; right? 11:19

25 A. I -- if that's how it's -- you 11:19

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1 interpreted it, it's -- that's not an accurate 11:19

2 statement. It's just notes that I had. I just 11:19

3 gave you my notes. Now what days they were on 11:19

4 specifically, that's what we're trying to 11:19

5 determine right now. 11:20

6 Q. And you're unable to do that. 11:20

7 A. Considering I didn't put a date at the 11:20

8 top, yeah. 11:20

9 Q. So let's look at Exhibit 152 -- 11:20

10 A. Okay. 11:20

11 Q. -- first; okay? 11:20

12 A. Okay. 11:20

13 Q. The top says "90 percent." What does 11:20

14 that mean? 11:21

15 A. I'm not really sure. I'm thinking that 11:21

16 it was a reference to listening to the question 11:21

17 like you've said and thinking about what's really 11:21

18 been said as opposed to jumping in and trying to 11:21

19 answer without really understanding the question. 11:21

20 So 90 percent of the effort would be sitting down, 11:21

21 listening to the question, and making sure that 11:21

22 you're answering in a way that's accurate. 11:21

23 Q. Under there it says, "defending turf." 11:21

24 What does that mean? 11:21

25 A. I believe that was guidance, since I 11:21

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1 have never done this before, that, you know, don't 11:21  
2 allow yourself to be headed down a direction that 11:22  
3 isn't the truth. So, again, I as said before, 11:22  
4 this is such -- so different than the 11:22  
5 collaborative stuff that -- that I've done in the 11:22  
6 past that obviously I need a little instruction on 11:22  
7 how to do this. 11:22

8 Q. Well, it would be great if this was 11:22  
9 collaborative. You're obviously getting guidance 11:22  
10 on how to make it combative; right? 11:22

11 MR. KERENSKY: Objection, form. 11:22

12 BY MR. ANDERTON: 11:22

13 Q. You may answer. 11:22

14 A. Could you say the question again? 11:22

15 MR. ANDERTON: Read it back, please, 11:22

16 Phil. 11:22

17 (Whereupon, the testimony was read 11:22  
18 back by the court reporter, as recorded above) 11:22

19 THE WITNESS: I wouldn't agree with that. 11:22

20 BY MR. ANDERTON: 11:22

21 Q. You don't think that somebody telling 11:22  
22 you to defend your turf isn't a guidance on how to 11:22  
23 make a process combative? 11:22

24 A. Absolutely not. 11:22

25 Q. Okay. In the next line there's a 11:22

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1 bracketed phrase that says "easier said than 11:23  
2 done." Is that what it says? 11:23  
3 A. Where are we at again? 11:23  
4 Q. The first page of Exhibit 152, top of 11:23  
5 the page. 11:23  
6 A. Easier said than done, yes. 11:23  
7 Q. What does that mean? 11:23  
8 A. To listen very carefully, things are in 11:23  
9 the box. To listen to the questions. Don't guess 11:23  
10 or propose a hypothesis and then the third and 11:23  
11 fourth thing. So that's what it is. It's very 11:23  
12 simple guidance, but it's, as I'm discovering, not 11:23  
13 real easy. 11:23  
14 Q. What do you mean by that? 11:23  
15 A. It's just hard work. 11:23  
16 Q. I think you're making it harder than it 11:23  
17 actually is, Dr. Bliesner, but that's just my 11:23  
18 humble opinion. 11:23  
19 The next page of Exhibit 152 says "write these 11:24  
20 down." 11:24  
21 A. Uh-huh. 11:24  
22 Q. Why did you make that note? 11:24  
23 A. I believe the conversation went to this 11:24  
24 effect, you know? How do you -- in your report, 11:24  
25 what are the things that come to mind off the top 11:24

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1 of your head that line up in some entry position 11:24  
2 outside of the report. So I went (witness makes 11:24  
3 noise) right off the top of my head. 11:24  
4 Q. So in essence what are the documents 11:24  
5 that support the conclusions in your report? 11:24  
6 A. Yeah. 11:24  
7 Q. And so they are the AERs, adverse event 11:24  
8 reports; right? 11:24  
9 A. Uh-huh. 11:24  
10 Q. The FDA documents; right? 11:24  
11 A. Yes. 11:24  
12 Q. Pharmacy complaints; right? 11:24  
13 A. Yes. 11:24  
14 Q. Deposition testimony? 11:24  
15 A. Yes. 11:24  
16 Q. Company responses to FDA inspections? 11:24  
17 A. Yes. 11:25  
18 Q. Company internal 11:25  
19 document/investigations? 11:25  
20 A. Yes. 11:25  
21 Q. Recall documents? 11:25  
22 A. Yes. 11:25  
23 Q. Mylan documents? 11:25  
24 A. Yes. 11:25  
25 Q. Deviation from standard industry 11:25

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1 practices? 11:25

2 A. Yes. 11:25

3 Q. Who created that list? 11:25

4 A. Me. 11:25

5 Q. In the moment in that meeting with 11:25

6 Plaintiffs' lawyers? 11:25

7 A. Yeah. 11:25

8 Q. Did they make suggestions on -- as to 11:25

9 what ought to be on the list? 11:25

10 A. Not really. 11:25

11 Q. Batch records isn't on that list, is it? 11:25

12 A. Specifically, no. 11:25

13 Q. "The big yes but tell me everything." 11:25

14 That notation can be seen on this page 2 of the 11:25

15 Exhibit 152; is that right? 11:25

16 A. Yes. 11:25

17 Q. What does that mean? 11:25

18 A. To tell you the truth, I have no idea. 11:25

19 Q. Your notes. 11:25

20 A. I know it's my notes, but I have no idea 11:25

21 what that means. I really don't. 11:25

22 Q. What does the bottom note say "and 11:25

23 that's dangerous"? 11:25

24 A. Yeah. 11:26

25 Q. What does that mean? 11:26

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1 A. To tell you the truth, I don't remember 11:26  
2 in this conversation. 11:26  
3 Q. Let's go look at Exhibit 153. 11:26  
4 A. Okay. 11:26  
5 Q. And let's look at the second page of 11:26  
6 Exhibit 153. 11:26  
7 A. Okay. 11:26  
8 Q. What is that list of six things? 11:26  
9 A. Looks like references to documents that 11:26  
10 are included in the report. 11:26  
11 Q. Who made the list? 11:26  
12 A. Well, I wrote the list. 11:26  
13 Q. Why? What's the intention of making the 11:26  
14 list? 11:26  
15 A. I'm trying to -- trying to remember. 11:26  
16 Q. Please do. 11:26  
17 A. Uh-huh. As we said before I'm pretty 11:26  
18 sure these are pages that went with the -- this 11:27  
19 set, the notes. I'm not sure when these notes 11:27  
20 were made, if it was with this or if it was this 11:27  
21 conversation because I don't have a time and a 11:27  
22 date on it, but it was some suggestions that if I 11:27  
23 wanted to -- in preparation for the deposition 11:28  
24 that the -- I go back and look at them since they 11:28  
25 were in my report -- by one of the attorneys. 11:28



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1 Q. So one of the attorneys -- the list on 11:28  
2 the second page of Exhibit 153 is a list of 11:28  
3 suggestions made by one of the lawyers for the 11:28  
4 Plaintiffs on things that you should go review 11:28  
5 prior to your deposition? 11:28

6 A. As I recall, yeah, they were 11:28  
7 suggestions. Just if I wanted to go back and look 11:28  
8 at it, yeah, I could, so... 11:28

9 Q. And somebody advised you to look for 11:28  
10 specific failures which resulted in blend 11:28  
11 uniformity; right? 11:28

12 A. No, I already had. They were just 11:28  
13 saying, you know, if I wanted to go back and 11:28  
14 review it, that they would suggest that. 11:28

15 Q. To look for specific failures which 11:28  
16 resulted in blend uniformity? 11:28

17 A. Right, which is in the report. 11:28

18 Q. What does that mean "look for specific 11:28  
19 failures which resulted in blend uniformity"? 11:28  
20 What I've just read is a quote from your notes. 11:28  
21 What does it mean? 11:28

22 A. It's not a quote. It's just my notes. 11:29

23 Q. I've read it. 11:29

24 A. I don't recall specifically what the 11:29  
25 guidance was on that. They made suggestions. If 11:29

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1 I want to review the documents, I did. I can tell 11:29

2 you this: Is that this list that is listed here 11:29

3 it was suggestions. I didn't go back and review 11:29

4 those documents. I just reviewed the report. 11:29

5 Q. I see on the right side about halfway 11:29

6 down that page. 11:29

7 A. Uh-huh. 11:29

8 Q. An underlined term "gross negligence." 11:29

9 Is that what it says? 11:29

10 A. It is. 11:29

11 Q. What does that mean? 11:29

12 A. Apparently that's a definition that one 11:29

13 of the attorneys gave me because I'd never heard 11:29

14 the term before. Somebody was talking about it 11:29

15 and I go what's that? So I jotted it down. Never 11:29

16 heard it before. 11:29

17 Q. Which attorney? 11:29

18 A. I don't know. 11:29

19 Q. What does it say underneath it. I can't 11:29

20 read that. Can you please read that for me? 11:29

21 A. I think it's supposed to be consequences 11:30

22 indifferent from -- I don't know those three 11:30

23 words. And welfare of persons involved in the 11:30

24 action with involved risk, suicide, injury, or 11:30

25 death. I just jotted it down quickly. 11:30

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1 Q. The consequences indifferent for the -- 11:30  
2 what's that word after "the"? 11:30  
3 A. I don't know. 11:30  
4 Q. For the health, perhaps? 11:30  
5 A. I don't know. 11:30  
6 Q. And welfare of the person involved? 11:30  
7 A. I -- I can't tell you. 11:30  
8 Q. You can't read your own writing? 11:30  
9 A. No, I can't. 11:30  
10 Q. One of the lawyers -- 11:30  
11 A. It was a term that came up and I go 11:30  
12 what's that? I never heard it before. So I just 11:30  
13 jotted it down. 11:30  
14 Q. Did they tell you to work it into one of 11:30  
15 your answers? 11:30  
16 A. No. 11:30  
17 Q. Did they tell you that it's a topic and 11:30  
18 a concept you should be familiar with as you 11:30  
19 responded to questions? 11:31  
20 A. Gross negligence? 11:31  
21 Q. Yes. 11:31  
22 A. No. 11:31  
23 Q. Did you use that term in your report 11:31  
24 ever? 11:31  
25 A. I would have to go back and review it. 11:31

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1 I don't think so. 11:31

2 Q. Well, Dr. Bliesner -- 11:31

3 A. Uh-huh. Because I've never heard it, 11:31

4 so... 11:31

5 Q. Dr. Bliesner, this is why this process 11:31

6 takes so long. 11:31

7 A. Okay. 11:31

8 Q. You tell me you've never heard the term 11:31

9 before this meeting which would have occurred long 11:31

10 after your report was prepared. 11:31

11 A. Uh-huh. 11:31

12 Q. Do you really have to go back and look 11:31

13 at your report to tell me whether that term is in 11:31

14 your report if you had never heard it before? Now 11:31

15 I understand that you prepared and were told to be 11:31

16 cautious in answering questions, but this process 11:31

17 takes as long as it does because of your 11:31

18 deliberately being difficult like that. 11:31

19 MR. KERENSKY: We don't need this kind of 11:31

20 speech, Mike. 11:31

21 MR. ANDERTON: What I need, Mike, is a 11:31

22 witness who will answer the questions that are 11:31

23 put to him. 11:31

24 MR. KERENSKY: Well, I think he's doing a 11:31

25 great job of that. And we don't need your 11:32

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1 speech. And really this is out of bounds. 11:32  
2 You ask all questions you want, but making 11:32  
3 speeches like this is highly objectionable. 11:32  
4 You're just trying to intimidate the witness, 11:32  
5 which will not work. 11:32  
6 MR. ANDERTON: I'm not trying to -- 11:32  
7 MR. KERENSKY: He's not intimidated and 11:32  
8 neither am I. 11:32  
9 MR. ANDERTON: I'm not trying to -- 11:32  
10 MR. KERENSKY: So why don't you just ask 11:32  
11 questions. 11:32  
12 MR. ANDERTON: Are you done, Mike? 11:32  
13 MR. KERENSKY: I'm done. 11:32  
14 MR. ANDERTON: I'm not trying to 11:32  
15 intimidate anyone. I'm merely trying to get 11:32  
16 this process to move forward. What we're 11:32  
17 going to see as we make our way through these 11:32  
18 notes is that Dr. Bliesner is holding very 11:32  
19 firmly to certain concepts he was -- that were 11:32  
20 given to him by the lawyers in this case and 11:32  
21 is deliberately being non-responsive. 11:32  
22 MR. KERENSKY: That's a total 11:32  
23 mischaracterization of what's going on here. 11:32  
24 BY MR. ANDERTON: 11:32  
25 Q. Dr. Bliesner, does the term gross 11:32

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1 negligence appear in your report? 11:32

2 A. Not that I recall. 11:32

3 Q. The next page of Exhibit 153. 11:33

4 A. Okay. 11:33

5 Q. Among other things is that same list 11:33

6 that we saw in Exhibit -- well, yeah. This 11:33

7 appears to be the same or a similar list that we 11:33

8 saw in Exhibit 152. 11:33

9 Do you see that? 11:33

10 A. This down here at the bottom? 11:33

11 Q. Yeah. 11:33

12 A. No. 11:33

13 Q. About the same list, isn't it? 11:33

14 A. Yeah, it looks like it. This would be a 11:33

15 transcript of this that was more readable. 11:33

16 Q. Okay. 11:33

17 A. Uh-huh. 11:33

18 Q. On the middle of the right side of this 11:33

19 page it says, "my top list." What does that mean? 11:33

20 A. I'm sorry. Where are we talking about? 11:34

21 Q. The middle of that page. It's the third 11:34

22 page of Exhibit 153. 11:34

23 A. The third page? 11:34

24 Q. Middle right side, about halfway down, 11:34

25 right edge, it says "my top list." What does that 11:34

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1 mean? 11:34

2 A. That was the list that I came up with 11:34

3 off the top of my head. 11:34

4 Q. The next page of that same Exhibit 153 11:34

5 is note that says, "are you aware of the fact that 11:34

6 FDA" and then a semi-colon. What does that mean? 11:34

7 A. I have no idea. 11:34

8 Q. The next item, number two, says 11:34

9 "possible equals we loose." I assume that you 11:34

10 meant to say "we lose." 11:34

11 A. I believe that's what it was intended to 11:34

12 be. 11:34

13 Q. So "loose" is a misspelling of "lose"? 11:34

14 A. I would assume that's correct, yes. 11:34

15 Q. "Possible equals we lose." What does 11:34

16 that mean? 11:35

17 A. I believe it was one of the attorneys 11:35

18 talking about trying to define for me "possible" 11:35

19 and "probable" because I didn't understand it. 11:35

20 Q. So you then -- well, so you discussed 11:35

21 with Plaintiffs' counsel the difference between 11:35

22 "possible" and "probable," right? 11:35

23 A. Yes. 11:35

24 Q. And you didn't understand it before that 11:35

25 conversation; right? 11:35

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1 A. That's correct. In legal terms. 11:35

2 Q. Did you understand it after that 11:35

3 conversation? 11:35

4 A. I still think I had difficulty with it 11:35

5 up until the deposition because Mr. -- what was 11:35

6 the other gentleman's name? Moriarty? 11:35

7 Q. Yeah, Moriarty. 11:35

8 A. Yeah. We went back and forth on it so I 11:35

9 was still a little bit cloudy at that stage of the 11:35

10 game. 11:36

11 Q. Okay. A little bit cloudy? You said 11:36

12 you had no idea. 11:36

13 A. No. Gross negligence. 11:36

14 Q. No. When you were being examined by 11:36

15 Mr. Moriarty, you said you had no notion of the 11:36

16 difference between probable and possible. 11:36

17 A. I don't recall being that definitive. 11:36

18 We could look it up in the transcript. 11:36

19 Q. Well, we can. The record will show what 11:36

20 it shows. 11:36

21 A. Okay. 11:36

22 Q. But what you're now saying is you 11:36

23 actually discussed that distinction with 11:36

24 Plaintiffs' counsel the day before you were 11:36

25 deposed. 11:36



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1 A. Yes. 11:36

2 Q. And they did such a great job in that 11:36

3 discussion that you came to that deposition still 11:36

4 having no idea. 11:36

5 A. Apparently they didn't prepare me very 11:36

6 well, did they? 11:36

7 MR. KERENSKY: Oh, sorry. 11:36

8 BY MR. ANDERTON: 11:36

9 Q. Now back to the substance of this 11:36

10 comment. "Possible equals we lose." You've told 11:36

11 me that that jars your recollection that you were 11:36

12 discussing the difference between probability and 11:36

13 possibility with Plaintiffs' counsel. 11:36

14 Now tell me what that means. 11:36

15 A. Probable, according to my notes and as I 11:37

16 understand it now, probable means there's a 11:37

17 reasonable degree of a certainty. 11:37

18 Q. Dr. Bliesner? 11:37

19 A. Yes. 11:37

20 Q. Pay attention to my question and answer 11:37

21 my question or we're going to be here all day, and 11:37

22 we're going to be back for a third session. 11:37

23 A. Okay. 11:37

24 Q. Tell me what your note, "possible equals 11:37

25 we lose" means. I didn't ask you to define 11:37

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1 probable versus possible. I ask you now for the 11:37

2 third time to tell me what your note means. 11:37

3 A. I'm thinking about it because it was -- 11:37

4 Q. Take as much time as you need to think 11:37

5 about it, but answer that question. 11:37

6 A. I will. Can I get some more water, 11:37

7 please? 11:37

8 Q. Yes, you may. 11:37

9 A. Thank you. 11:37

10 MR. ANDERTON: Let's go off the record. 11:38

11 THE VIDEOGRAPHER: The time is 11:37 a.m. 11:38

12 We're going off the record. 11:38

13 (Short break) 11:38

14 THE VIDEOGRAPHER: Time is ; we're 11:38

15 back on the record. 11:38

16 MR. ANDERTON: Phil, will you read that 11:39

17 last question back, please? 11:39

18 (Whereupon, the testimony was read 11:39

19 back by the court reporter, as recorded above) 11:39

20 THE WITNESS: From what I recall in the 11:39

21 conversation, possible leaves room for doubt; 11:39

22 probable does not. And "may" leaves doubt. 11:39

23 So from protecting, what do they call them, 11:39

24 the client, that from a legal opinion, they 11:39

25 were trying to describe to me they thought 11:39

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1 that the cases would not stand up if it was 11:39

2 possible or may. 11:39

3 BY MR. ANDERTON: 11:39

4 Q. So if you -- so you were told by the 11:39

5 Plaintiffs' counsel that if you acknowledged 11:39

6 something was only possible, Plaintiffs would 11:39

7 lose? 11:39

8 A. The conversation as I recall in this 11:39

9 discussion was I need to determine in my mind 11:39

10 based on my report and the data that I looked at 11:39

11 those three things. 11:40

12 Q. I understand that. 11:40

13 A. Yes. 11:40

14 Q. But you were told that if you answer a 11:40

15 question and acknowledge something was possible, 11:40

16 Plaintiffs would lose; right? 11:40

17 A. Yes. 11:40

18 Q. And if you answered a question and 11:40

19 acknowledged that something -- if you said may? 11:40

20 A. Yes. 11:40

21 Q. Instead of probable, Plaintiffs would 11:40

22 lose. 11:40

23 A. Yes. 11:40

24 Q. So you were told not to answer questions 11:40

25 as possible or may, if possible; right? 11:40

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1 A. No, that's not true at all. 11:40

2 Q. It isn't? 11:40

3 A. I was told specifically these are the 11:40

4 conditions that may lead to "lose," if you will; 11:40

5 all right? And that I needed to make sure where I 11:40

6 was comfortable with respect to my report on those 11:40

7 definitions, and it was up to me. 11:40

8 Q. And how does -- how does your comfort 11:40

9 with respect to your report factor into whether 11:40

10 the Plaintiffs are going to lose or not? That's 11:40

11 not something you considered in drafting your 11:40

12 report, is it? 11:40

13 A. Could you say that again, please? I'm 11:40

14 not being a pain. I'm just trying to. 11:40

15 MR. ANDERTON: Phil would be happy to 11:40

16 read that back to you. 11:40

17 (Whereupon, the testimony was read 11:40

18 back by the court reporter, as recorded above) 11:40

19 THE WITNESS: No, not at all. I didn't 11:41

20 consider win or loss or anything. I reviewed 11:41

21 the data, I put together a report, I drew 11:41

22 conclusions based on the documents that I had 11:41

23 reviewed, and that was it. 11:41

24 BY MR. ANDERTON: 11:41

25 Q. And as you prepared for the deposition 11:41

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1 and to be asked questions about the analysis and 11:41  
2 conclusions reached, you were told to consider 11:41  
3 whether Plaintiffs would lose. 11:41

4 A. They said words to the effect, if I 11:41  
5 recall, be aware that if you use these words this 11:41  
6 is what it means from a legal term. Because 11:41  
7 apparently I didn't understand the difference 11:41  
8 between probable and possible. That's what they 11:41  
9 said. 11:41

10 Q. So you were told that if you said 11:41  
11 possible rather than probable, it would mean 11:42  
12 Plaintiffs would lose? 11:42

13 A. Potentially, yes. But I was not 11:42  
14 directed to specifically use those words or not 11:42  
15 use those words. It was me. 11:42

16 Q. I understand. And were you also told if 11:42  
17 you say "may" rather than "probable," Plaintiffs 11:42  
18 would lose? 11:42

19 A. According to my notes, yes. 11:42

20 Q. I want you to tell me if that's what you 11:42  
21 were told, Dr. Bliesner. 11:42

22 A. I was told that, yes. 11:42

23 Q. Okay. Below that -- 11:42

24 A. Uh-huh. 11:42

25 Q. -- there's a bracketed or kind of like 11:42

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1 an almost box. It says "problem could be with." 11:42

2 That's W/sub potent for blend uniformity. What 11:42

3 does that mean? 11:42

4 A. I think one of the attorneys asked me 11:42

5 that question so I just jotted it down. 11:42

6 Q. Who asked you? 11:43

7 A. I don't recall. 11:43

8 Q. You just jotted down the question they 11:43

9 asked you? 11:43

10 A. I did, yeah. There was points where 11:43

11 they asked think about this. Okay. So I jotted 11:43

12 it down. 11:43

13 Q. So they told you that -- they told you 11:43

14 that as you answered -- listened to and answered 11:43

15 questions, you should -- you should remember that 11:43

16 the problem -- I assume that means with Digitek -- 11:43

17 could be with a blend uniformity or a sub-potent 11:43

18 product; right? 11:43

19 A. No, I don't think that's the case 11:43

20 necessarily. There was instruction going on here 11:43

21 with attorneys on top of it all. So some of this 11:43

22 was, you know, go back, make a note of it, go back 11:43

23 and explain to them my interpretation because they 11:43

24 hadn't been exposed to any of this stuff before. 11:43

25 Q. "They" who? 11:43

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1 A. The attorneys. They don't understand 11:43  
2 some of the subtleties in the manufacturing arena. 11:43

3 Q. So your testimony is that on the day 11:43  
4 before your deposition, almost three years into 11:43  
5 this litigation, you felt that the Plaintiffs' 11:44  
6 lawyers you were working with needed guidance on 11:44  
7 something as basic as whether something was 11:44  
8 sub-potent or whether there was a blend uniformity 11:44  
9 issue? 11:44

10 A. I can't state to that fact. I know 11:44  
11 there were two new people in the room -- mike and 11:44  
12 what was the other gentleman's name? -- and they 11:44  
13 asked me questions so I jotted them down. 11:44

14 Q. Well, Dr. Bliesner -- 11:44

15 A. Uh-huh. 11:44

16 Q. -- this is one of those situations where 11:44  
17 it seems to me like you kind of want to have it 11:44  
18 both ways. When I ask you a specific question and 11:44  
19 said -- and asked whether this is what that means, 11:44  
20 you said no, that's not what it means. When I ask 11:44  
21 you generally what it means, you respond by saying 11:44  
22 "I don't know." 11:44

23 MR. KERENSKY: Objection, form. 11:44

24 BY MR. ANDERTON: 11:44

25 Q. So, I mean -- 11:44

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1 A. I cannot definitively tell you where 11:44  
2 this statement fits into this conversation. I 11:44  
3 just cannot. 11:44

4 Q. Okay. The next -- below that on the 11:44  
5 left side there's like a phrase that says 11:44  
6 "conscious indifference." "Gross negligence." 11:45  
7 Do you see that? 11:45

8 A. Yes. 11:45

9 Q. Why did you write that? 11:45

10 A. Because they were terms that they were 11:45  
11 throwing around. So I jotted them down so I could 11:45  
12 try to figure out what it meant. 11:45

13 Q. On the very bottom right corner -- don't 11:45  
14 turn the page just yet, Dr. Bliesner. 11:45

15 A. Sorry. 11:45

16 Q. There's another bracketed phrase that 11:45  
17 says, "what is the likelihood of blend uniformity 11:45  
18 causing these super of sub-potent." I assume 11:45  
19 that's supposed to be super or sub potent? 11:45

20 A. I'm thinking that's probably what it was 11:45  
21 supposed to be. 11:45

22 Q. All right. So why did you make that 11:45  
23 note? 11:45

24 A. I don't know. I don't recall why I made 11:45  
25 that note. Again, it might have been a question 11:45



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1 from one of the attorneys or. 11:45

2 Q. Did you discuss with the Plaintiffs' 11:45

3 counsel on the 24th the notion of the difference 11:45

4 between double-thick tablets and tablets that were 11:45

5 either super or sub-potent? 11:45

6 A. The difference between? 11:46

7 Q. Yeah. 11:46

8 A. I don't recall that conversation, the 11:46

9 difference between. 11:46

10 Q. Did they tell you to make sure that you 11:46

11 kept the door open -- to use your terminology -- 11:46

12 to give testimony that there were either super 11:46

13 potent or sub-potent tablets produced? 11:46

14 A. Do we need to read this back? 11:46

15 Q. We do, please. 11:46

16 A. Okay. 11:46

17 (Whereupon, the testimony was read back 11:46

18 by the court reporter, as recorded above) 11:46

19 THE WITNESS: I don't recall being 11:46

20 specifically asked to leave the door open or 11:46

21 that issue in particular with respect to super 11:46

22 or sub-potent. 11:46

23 MR. ANDERTON: Okay. I need to go off 11:46

24 the record for about 30 seconds. Mike, stay 11:47

25 close. 11:47

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1 THE VIDEOGRAPHER: The time is 11:47  
2 11:46 a.m. We're going off the record 11:47  
3 briefly. 11:47  
4 (Short break) 11:47  
5 THE VIDEOGRAPHER: The time is 11:47  
6 a.m. We're back on the record. 11:47  
7 BY MR. ANDERTON: 11:47  
8 Q. All right. So turn to the next page of 11:47  
9 Exhibit 153, Dr. Bliesner. 11:47  
10 A. Yes. 11:47  
11 Q. On the top it says, the second line of 11:47  
12 that next page it says "think:" 11:47  
13 A. Uh-huh. 11:47  
14 Q. "Can I ask this question?" What does 11:47  
15 that mean? 11:48  
16 A. I think I had a question can I ask -- as 11:48  
17 I'm being deposed, can I ask questions back of the 11:48  
18 people who are asking me questions. 11:48  
19 Q. What did they tell you? 11:48  
20 A. They said no, you're pretty much 11:48  
21 supposed to sit there and answer questions, if I 11:48  
22 remember right. 11:48  
23 Q. Okay. 11:48  
24 A. Uh-huh. 11:48  
25 Q. Next a little bit below that it says 11:48

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1 "tell me all" with an extended ellipses, and then 11:48  
2 it says, "give them roman numerals." What does 11:48  
3 that mean? 11:48  
4 A. That's the lists that we came up with. 11:48  
5 Q. Okay. "We" came up with? 11:48  
6 A. Well, I gave it. Somebody wrote it on 11:48  
7 the board as I was saying it. 11:48  
8 Q. Oh, you had a white board? 11:48  
9 A. Uh-huh. 11:48  
10 Q. Where was this? 11:48  
11 A. The conference room. 11:48  
12 Q. Where? 11:48  
13 A. In the hotel next door. 11:48  
14 Q. At the Hyatt? 11:48  
15 A. What was it? Sheraton, I believe. 11:48  
16 Q. Okay. 11:48  
17 A. Uh-huh. 11:48  
18 Q. Who was writing on the board? 11:48  
19 A. At that time? I think it was Mike. 11:48  
20 Q. Mike Kerensky? 11:49  
21 A. Yes. 11:49  
22 Q. I'm sorry I missed that. 11:49  
23 So what -- help me out here with context, 11:49  
24 then. You were collectively generating a list and 11:49  
25 the list that is set forth in Roman numerals in 11:49

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1 Exhibit 152? 11:49

2 A. Yes. 11:49

3 Q. And then you wrote them down as you 11:49

4 collectively generated that list? 11:49

5 A. As I was pontificating, somebody said 11:49

6 oh, okay. I believe it was, if I recall, Mike 11:49

7 just writing it down. It was all off the top of 11:49

8 my head. 11:49

9 Q. Well, but -- okay. 11:49

10 A. Uh-huh. 11:49

11 Q. Go to the next page. The very last page 11:50

12 of Exhibit 153. 11:50

13 A. Last page? 11:50

14 Q. Yeah. And let me ask you this: 11:50

15 A. Uh-huh. 11:50

16 Q. Have you given a copy of these notes to 11:50

17 the lawyers? 11:50

18 A. I don't know. I really don't know if 11:50

19 they've got a copy of it. 11:50

20 Q. You would have made the copies; right, 11:50

21 Dr. Bliesner? 11:50

22 A. Not necessarily. 11:50

23 Q. Your wife would have made them for you? 11:50

24 A. The notes were done in the conference 11:50

25 room when we prepped the day before. 11:50

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1 Q. And you think the lawyers maybe took 11:50  
2 them and made copies of them? 11:50  
3 A. I have no idea. They perhaps could 11:50  
4 have. 11:50  
5 Q. On that last page -- 11:50  
6 A. Uh-huh. 11:50  
7 Q. -- number two says NTI. I take it 11:51  
8 that's supposed to mean narrow therapeutic index? 11:51  
9 A. I don't know. 11:51  
10 Q. You don't know? 11:51  
11 A. I really don't. 11:51  
12 Q. Bracket references the EIR 2008, "95 11:51  
13 pages. Will ask." What does that mean? 11:51  
14 A. I don't know. 11:51  
15 Q. At the very bottom it says, "Pills 11:51  
16 probably got out there." 11:51  
17 Do you see that? 11:51  
18 A. I do. 11:51  
19 Q. You wrote that; right? 11:51  
20 A. I did write that. 11:51  
21 Q. What's it mean? 11:51  
22 A. It means at the end of the day, after 11:51  
23 looking at my report again and having these 11:51  
24 discussions that I was convinced that it was 11:51  
25 probable that more than just two or three or 11:52

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1 whatever, double-thick or whatever, thin tablets 11:52  
2 that were out there got out there. I was 11:52  
3 convinced with the data. 11:52

4 Q. Which brings us back to the underlying 11:52  
5 question that prompted all of this. 11:52

6 A. Uh-huh. 11:52

7 Q. Your opinion indicates that you believe 11:52  
8 adulterated product reached the market. 11:52

9 A. Well, we know it reached the market. We 11:52  
10 have a couple of circumstances where we know that 11:52  
11 it did. 11:52

12 Q. Okay. And when you say a couple of 11:52  
13 circumstances, you're talking about the 2004 11:52  
14 circumstance and the 2008 allegations that 11:52  
15 double-thick tablets reached the market. 11:52

16 Am I correct about that? 11:52

17 A. Not necessarily because we stopped 11:52  
18 sometime back going through, picking out to make 11:52  
19 sure that there was other points other than what 11:52  
20 you're pointing out right there. 11:53

21 Q. Are you aware of any other circumstances 11:53  
22 that suggest to you that we -- that you know 11:53  
23 double-thick tablets reached the market? 11:53

24 A. In your original question -- 11:53

25 Q. I'm asking you that question now. 11:53

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1 A. Unless I finish reviewing this report, I 11:53  
2 can't answer that question. 11:53  
3 MR. ANDERTON: Let's go off the record 11:53  
4 and allow you to do that. 11:53  
5 THE VIDEOGRAPHER: The time is now 11:53  
6 a.m. We're going off the record 11:53  
7 briefly. 11:53  
8 (Short break) 12:01  
9 THE VIDEOGRAPHER: The time is 12:01  
10 p.m. We are back on record. 12:01  
11 BY MR. ANDERTON: 12:01  
12 Q. Dr. Bliesner, I asked you a question or 12:01  
13 I started to ask you a question about your 12:01  
14 opinions in this case. 12:01  
15 A. Uh-huh, yes. 12:01  
16 Q. And in response you said "we know". 12:01  
17 Know -- 12:02  
18 A. Uh-huh. 12:02  
19 Q. -- adulterated product reached the 12:02  
20 market. 12:02  
21 A. Yes. 12:02  
22 Q. I then asked you the basis for your 12:02  
23 testimony that we know adulterated product reached 12:02  
24 the market and you said -- you asked to review 12:02  
25 your report which you just did; right? 12:02

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1 A. Yes. 12:02

2 Q. Have you reviewed your report and are 12:02

3 you able to answer my questions on how we know or 12:02

4 you think you know adulterated product reached the 12:02

5 market? 12:02

6 A. I have a -- general idea is to go back 12:02

7 and specifically look at the wording, I would have 12:02

8 to go to the appendices, but I can give you the 12:02

9 references. 12:02

10 Q. You've got a 90-some page document in 12:02

11 front of you. 12:02

12 A. Yes. 12:02

13 Q. You need to go outside that 90-page 12:02

14 document to answer my question about how we -- how 12:02

15 you think you know adulterated product reached the 12:02

16 market? 12:02

17 A. Yeah, I want to make sure I'm answering 12:02

18 the question completely. 12:02

19 Q. Well, tell me what you know from 12:03

20 reviewing the report. 12:03

21 A. From reviewing the report on page 79, 12:03

22 number 12, that there was a Class II recall 12:03

23 initiated through variation in tablet size 12:03

24 resulting in sub or super potent drug product, 12:03

25 according to reference attachment D5. 12:03



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1 Q. Was that Digitek? 12:03  
2 A. I don't recall. I'd have to look it up. 12:03  
3 Q. What was the year of that? 12:03  
4 A. 1990. 12:03  
5 Q. 1990? 12:03  
6 A. Uh-huh. 12:03  
7 Q. 21 years ago? 12:03  
8 A. Yes. 12:03  
9 Q. Okay. What else do you know from 12:03  
10 reviewing your report? 12:03  
11 A. Page 81, June 2004, complaint received 12:03  
12 from a pharmacist in Bellingham, Washington, 12:03  
13 regarding thick Digoxin tablet. MI confirms 12:03  
14 thickness. No definitive root cause found. 12:04  
15 Q. 2004, a single tablet; right? 12:04  
16 A. I would have to look at the reference to 12:04  
17 determine whether it was one tablet or not. 12:04  
18 Q. Dr. Bliesner, this is your report; 12:04  
19 right? 12:04  
20 A. It is my report, yes, sir. 12:04  
21 Q. Now this is why this takes so long. Is 12:04  
22 it more than a single tablet? 12:04  
23 MR. KERENSKY: He doesn't need be 12:04  
24 lectured about how long it takes. We need you 12:04  
25 to ask questions. 12:04

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1 MR. ANDERTON: I need him to answer 12:04  
2 questions, Mike. 12:04  
3 MR. KERENSKY: He's answering them. 12:04  
4 MR. ANDERTON: No, he's not. 12:04  
5 MR. KERENSKY: Well, when you ask a real 12:04  
6 broad question about tell me everything you 12:04  
7 know, it's going to take time, bro? 12:04  
8 MR. ANDERTON: Bro? 12:04  
9 MR. KERENSKY: Bro. 12:04  
10 BY MR. ANDERTON: 12:04  
11 Q. Dr. Bliesner. 12:04  
12 A. Yes. 12:04  
13 Q. Your report on page 81 refers to a 12:04  
14 single thick tablet; right? 12:04  
15 A. Unless I go back and pull up those 12:05  
16 reference, I can't tell you whether it's one or 12:05  
17 more. 12:05  
18 Q. You can't? 12:05  
19 A. No, definitively. I would be guessing 12:05  
20 unless I go back to that primary reference. 12:05  
21 Q. All right. Moving on. 12:05  
22 What else from your report supports your 12:05  
23 conclusion that adulterated Digitek reached the 12:05  
24 market? 12:05  
25 A. On page 87. 12:05

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1 Q. Yeah? 12:05

2 A. And this is where I would have to go 12:05

3 back and specifically look because I'm not sure 12:05

4 whether these are returned products or not, but 12:05

5 overweight tablets were found during packaging; 12:05

6 okay? That one I'm... 12:05

7 Q. What number are you referring to? 12:05

8 A. 47, 47. 12:05

9 Q. 47? 12:05

10 A. Yeah. A39 reference. That's why I 12:05

11 wanted to look at it because I'm not sure whether 12:05

12 that has to do with stuff that made it to the 12:05

13 market or they caught it within the facility. 12:06

14 Q. Would reference number 47, your 12:06

15 reference number 47 tell you that? 12:06

16 A. A39. 12:06

17 Q. I'm sorry. Would that tell you whether 12:06

18 it made it to market? 12:06

19 A. More than likely whether this was done 12:06

20 internally and it wasn't returned. 12:06

21 Q. Okay. What else from your report? 12:06

22 A. Number 49 on page 84, Mylan acknowledges 12:06

23 pharmacist identifying double-thick product in 12:06

24 marketplace. 12:06

25 Q. Okay. 12:06

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1 A. A58. 12:06

2 Q. Anything else? 12:06

3 A. From what I can see, no. 12:06

4 Q. Okay. Now, this binder -- oh, Phil 12:06

5 would you mark this, please? 12:06

6 (Whereupon, Exhibit 154 was marked for 12:07

7 identification) 12:07

8 Dr. Bliesner, will you look at the binder 12:07

9 that's marked as Exhibit 154 and find your 12:07

10 reference attachment A36, please. I'm sorry. I 12:07

11 misspoke. A39, please. 12:07

12 Did you find A36? 12:08

13 A. I'm just double checking here. Does not 12:08

14 appear to be the direct reference that I thought 12:08

15 it was going to. 12:08

16 Q. I'm sorry. A39. I misspoke again. Did 12:08

17 you find A39? 12:08

18 A. I did find A39, but it does not appear 12:08

19 to me to be the reference that I referenced 12:08

20 here -- A39. 12:08

21 Q. What is A39, Doctor? 12:09

22 A. A39 is response to the FDA 483 issued to 12:09

23 Activis on 5/20/2008. 12:10

24 Q. Let's not take our common sense hats 12:10

25 off; okay? Let's think about this logically. 12:10

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1 A. Okay. 12:10

2 Q. Your paragraph 47 on page 87 of your 12:10

3 report refers to an investigation of Digoxin 12:10

4 tablets, lot 8022881. 12:10

5 A. Uh-huh. 12:10

6 Q. For overweight tablets -- 12:10

7 A. Uh-huh. 12:10

8 Q. -- which were found during packaging 12:10

9 right? 12:10

10 A. Uh-huh. 12:10

11 Q. You have to say yes or no, please. 12:10

12 A. Yes, I'm sorry. 12:10

13 Q. Okay. 12:10

14 A. I'm sorry. 12:10

15 Q. Do you cite that as support in your 12:10

16 report, in the body of your conclusion that 12:10

17 product actually made it to market? 12:10

18 A. What I was asked to review, I was asked 12:10

19 to pick out things and I'm not sure whether these 12:10

20 were picked up in site or they were returned 12:10

21 products or something like that. 12:10

22 Q. Now answer my question. 12:10

23 A. Okay. 12:10

24 Q. Do you cite that batch and the 12:10

25 circumstances -- and any circumstances relating to 12:10

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1 that batch in the body of your report as an 12:11  
2 indication that product -- defective product or 12:11  
3 adulterated product made it to market? 12:11

4 A. This is the citation. Criminal 12:11  
5 investigation, QA hold pending. 12:11

6 Q. Dr. Bliesner. 12:11

7 A. I'm trying to answer your question, sir. 12:11

8 Q. I asked you if you cite it in your 12:11  
9 report. You're now looking at something other 12:11  
10 than your report. 12:11

11 A. Right, because I've got to go back -- 12:11

12 Q. How do you determine -- 12:11

13 A. Because I want to see where the 12:11  
14 investigation is, if it's cited in the reference 12:11  
15 to make sure that the reference is correct. 12:11

16 Q. Okay. 12:12

17 A. Okay? 12:12

18 Q. Okay. 12:12

19 A. I'm not messing with you. 12:12

20 Q. You actually are. 12:12

21 A. I'm just trying to get the right 12:12  
22 answer. No, sir, I'm not. 12:12

23 That reference does not support the statement 12:15  
24 that product made it to market. That specific 12:15  
25 reference does not. 12:15

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1 Q. Okay. 12:15

2 A. Okay. 12:15

3 Q. So -- well, suffice to say, 12:15

4 Dr. Bliesner, that there's ample information out 12:16

5 there in the record making very clear that that 12:16

6 batch was in fact rejected and never went to 12:16

7 market. 12:16

8 You don't have any information that 12:16

9 contradicts that, do you? 12:16

10 A. Not to my knowledge, no. 12:16

11 Q. Okay. So, if that batch was rejected 12:16

12 that -- that -- the circumstances relating to or 12:16

13 set forth in your paragraph 47 on page 18 of your 12:16

14 report do not constitute any evidence that 12:16

15 defective or adulterated Digitek -- I want to make 12:16

16 this clear. That adulterated Digitek actually 12:16

17 made it to market, did they? 12:16

18 A. That is correct. 12:16

19 Q. Okay. You also referred to -- and so 12:16

20 that we're clear, you also made reference to that 12:16

21 batch 8022801 from paragraph 47 on page 87. So 12:17

22 your prior testimony about that possibly 12:17

23 supporting a statement that we know adulterated 12:17

24 product made it to market, that's not accurate 12:17

25 with respect to any circumstances relating to 12:17

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1 batch 8022801, is there? 12:17

2 A. What page was that? 12:17

3 Q. 87. 12:17

4 A. No, it's the same -- same statement. 12:17

5 It's just information put in a different place. 12:17

6 Q. Okay. 12:17

7 A. Uh-huh. 12:17

8 Q. All right. 12:17

9 A. We were going to check on number 49. 12:17

10 Q. We'll get there. 12:17

11 A. Okay. 12:17

12 Q. The -- Dr. Bliesner, so we've eliminated 12:17

13 batch 80228. The circumstances in 2004 where a 12:18

14 pharmacist found a tablet in the market, was that 12:18

15 part of the recalled product? 12:18

16 A. Which recall? 12:18

17 Q. The 2008 recall of Digitek. 12:18

18 A. The product for the? 12:18

19 Q. The tablet that was found in the market 12:18

20 in 2004, was that part of the recalled product? 12:18

21 A. Not to my knowledge. 12:18

22 Q. The expiration period for this product 12:18

23 is two years. Are you aware of that? 12:18

24 A. I am not. 12:18

25 Q. Okay. You'll take my word for it? 12:18



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1 A. I'll take your word for it. 12:18

2 Q. So if a tablet was found in the market 12:18

3 in 2004 and was manufactured no later than 2004 12:18

4 and therefore was no longer in the market and 12:18

5 within expiration as of 2008; correct? 12:18

6 A. 2004, two years I would say yes, that's 12:18

7 fair. 12:18

8 Q. Okay. And again, there's plenty of 12:19

9 evidence out there that speaks to what or was not 12:19

10 part of the recall product. 12:19

11 Which leaves us -- and the 1990 circumstances 12:19

12 certainly have nothing, no -- none of the product 12:19

13 that was involved in the circumstances you cited 12:19

14 in 1990 were part of the 2008 recall; correct? 12:19

15 A. Not part of the 2008 recall, no. 12:19

16 Q. Okay. All right. 12:19

17 A. It may have impacted the product, 12:19

18 though. 12:19

19 THE VIDEOGRAPHER: We've got five minutes 12:19

20 left on the tape. 12:19

21 BY MR. ANDERTON: 12:19

22 Q. Okay. It may have impacted what 12:19

23 product? 12:19

24 A. We're not sure because the reference is 12:19

25 just for a recall for double-thick, double thin. 12:19

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1 The information I was provided doesn't 12:19  
2 specifically say what the product is. 12:19

3 Q. Okay. 12:19

4 A. There was indications that they've had 12:19  
5 problems with double-thick, double thin or thin or 12:19  
6 thick tablets in days gone by in the manufacturing 12:19  
7 process. 12:19

8 Q. And so you're willing to infer that 12:19  
9 something that happened in 1990 was still 12:19  
10 occurring in 199-- or in 2008, 18 years later? 12:19

11 A. I think it's fair to say that the 12:20  
12 information that's there in documents that I 12:20  
13 reviewed showed that the same people who were in 12:20  
14 charge of the quality and manufacturing back then 12:20  
15 are the same people that were there later down the 12:20  
16 road. The same processes -- I'm trying to think 12:20  
17 when the ANDAs were, the equipment was. So if 12:20  
18 people and equipment were in place and obviously 12:20  
19 they had problems with quality systems difficulty, 12:20  
20 else they wouldn't have had all the problems with 12:20  
21 the FDA. 12:20

22 So there were documented problems with the 12:20  
23 quality systems, same people and mostly like the 12:20  
24 same equipment on the stuff that occurred later 12:20  
25 on. 12:20

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1 Q. Okay. Who was the director of 12:20  
2 manufacturing in 2008, do you know? 12:20  
3 A. I'd have to go back. 12:20  
4 Q. I'm sorry. In 2007. 12:20  
5 A. I'd have to go back and look at that. 12:20  
6 Q. It was Rick Dowling. 12:20  
7 A. Okay. 12:20  
8 Q. You'll take my word for that? 12:20  
9 A. Sure. 12:20  
10 Q. When was Rick Dowling hired? 12:20  
11 A. I'd have to go back and look that up. 12:20  
12 Q. Was he employed in 1990? 12:20  
13 A. I'd have to go back and look it up. 12:20  
14 Q. Because Activis in 1990 was Amide; 12:21  
15 correct? 12:21  
16 A. I believe it was. 12:21  
17 Q. Were they making Digitek as of 1990? 12:21  
18 A. I'd have to look that up, but it's a 12:21  
19 possibility they were. 12:21  
20 Q. It is? 12:21  
21 A. Yes. 12:21  
22 Q. Their ANDA was approved when? 12:21  
23 A. They were releasing product by the batch 12:21  
24 release certification process back then. So they 12:21  
25 submitted and sold product based on that and not 12:21

Page 411

1 the ANDA. 12:21

2 Q. If it's true -- 12:21

3 A. Uh-huh. 12:21

4 Q. -- that Activis -- or Amide rather -- 12:21

5 wasn't making Digoxin until 1995, then the 1990 12:21

6 circumstances have no bearing on your conclusion 12:21

7 that adulterated Digitek -- that your supposed 12:21

8 conclusion that we know adulterated Digitek made 12:21

9 it to market; correct? 12:21

10 A. I don't know if I understand that 12:21

11 question. 12:21

12 Q. You don't understand it because it was a 12:21

13 very poorly worded question. So I'm going to 12:21

14 start that one over. 12:22

15 If it's true that Amide didn't start 12:22

16 manufacturing Digitek until 1995, then the 12:22

17 circumstances you refer to about a 1990 recall 12:22

18 have nothing to do with your conclusion in your 12:22

19 report that we know adulterated Digitek reached 12:22

20 the market; correct? 12:22

21 A. I don't think you can say that. 12:22

22 Q. They weren't making it. 12:22

23 A. They were making Digoxin very early on. 12:22

24 Q. Dr. Bliesner, if they didn't start 12:22

25 making it until 1995, they couldn't -- the recall 12:22

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1 in 1990 could not have been Digoxin; correct? 12:22

2 A. I'm not sure without going back and 12:22

3 reviewing the record when they actually started 12:22

4 making Digoxin tablets. 12:22

5 Q. Now answer my question. 12:22

6 A. Okay. 12:22

7 Q. If they didn't start making it until 12:22

8 1995, the 1990 recall circumstances could not have 12:22

9 been a recall of Digoxin; correct? 12:23

10 A. If they did not, that's correct. 12:23

11 Q. Okay. 12:23

12 A. If. But we don't know for sure. 12:23

13 Q. But we do, Dr. Bliesner. 12:23

14 A. We do? 12:23

15 Q. Okay. 12:23

16 A. Yes. 12:23

17 Q. We do. 12:23

18 THE VIDEOGRAPHER: You have about two 12:23

19 minutes left. 12:23

20 MR. ANDERTON: Let's break for lunch. 12:23

21 THE VIDEOGRAPHER: The time is 12:23

22 12:22 p.m. We're going off the record. 12:23

23 (Short break for lunch) 12:52

24 THE VIDEOGRAPHER: The time is now 12:52

25 12:52 p.m. We are back on the record. This 12:53

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1 is the beginning of tape five. 12:53

2 BY MR. ANDERTON: 12:53

3 Q. Dr. Bliesner, would you look at page 9 12:53

4 of your report, please? 12:53

5 A. Sure, yes. 12:53

6 Q. You see paragraph four on page 9? 12:53

7 A. Yes. 12:53

8 Q. That indicates that in June of 1995 the 12:53

9 FDA issued a certification to Amide which allowed 12:53

10 Amide to manufacture and sell Digoxin under the 12:53

11 batch certification program; right? 12:53

12 A. Correct. 12:53

13 Q. Does that refresh your recollection as 12:54

14 to when Amide began manufacturing and distributing 12:54

15 Digitek and whether it was as far back as 1990? 12:54

16 A. Yes. 12:54

17 Q. Okay. What we know now is that the 1990 12:54

18 recall was not Digitek or Digoxin; correct? 12:54

19 A. Most likely. 12:54

20 Q. And so then as I understand it, you 12:54

21 agree that the 2004 tablet was not part of the 12:54

22 recalled Digitek; right? 12:54

23 A. Based on expiration date and the fact 12:54

24 that it was two years and then later on, yes. 12:54

25 Q. The 1990 recall was not Digitek; right? 12:54

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1 A. Most likely, yes. 12:54

2 Q. And the 2008 batch 80228 was rejected 12:54

3 and never made it to market. That leaves the 12:54

4 tablet referenced in -- 12:55

5 A. Well, that was that -- just that one lot 12:55

6 that we talked about that was rejected. 12:55

7 Q. I understand. 12:55

8 A. Okay. 12:55

9 Q. But you've identified for me -- I gave 12:55

10 you a considerable amount of time. 12:55

11 A. Uh-huh. 12:55

12 Q. Let's back this up, Dr. Bliesner. 12:55

13 I asked you about your conclusion in this 12:55

14 case. 12:55

15 A. Uh-huh. 12:55

16 Q. And about the conclusion that 12:55

17 adulterated Digitek was released to market and you 12:55

18 said very clearly "we know that adulterated defect 12:55

19 made it to market." 12:55

20 A. Yes. 12:55

21 Q. I gave you almost a half hour to review 12:55

22 your report and other related documents to come up 12:55

23 with evidence which you believe indicates that you 12:55

24 know adulterated Digitek made it to market. 12:55

25 A. Uh-huh. 12:55

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1 Q. And you identified all of those 12:55

2 instances and circumstances; right? 12:55

3 A. With the information I have reviewed, 12:55

4 yes. 12:55

5 Q. Okay. And you've identified everything 12:55

6 that you're aware of; correct? 12:56

7 A. In the documents that I was -- reviewed, 12:56

8 yes. 12:56

9 Q. Dr. Bliesner. 12:56

10 A. Yes. 12:56

11 Q. Have you identified every instance that 12:56

12 you are aware of where you believe adulterated 12:56

13 Digitek made it to market? 12:56

14 A. In the documents I reviewed, yes. 12:56

15 Q. Doctor -- 12:56

16 A. There may be other documents out there 12:56

17 that would support the -- 12:56

18 Q. Are you aware of those? 12:56

19 A. I haven't reviewed everything that's on 12:56

20 there, been put out. So I can't -- I can't say 12:56

21 whether I'm aware of it or not. 12:56

22 Q. If you haven't reviewed it, can you be 12:56

23 aware of what's in it? Is that possible? 12:56

24 A. No, that's what I'm saying. There are 12:56

25 additional documents and reports and things like 12:56



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1 that I'm sure have since become available and I 12:56  
2 have not reviewed it. The documents that I 12:56  
3 reviewed, the statement is correct. 12:56

4 Q. We're going to stay here all afternoon 12:57  
5 until you answer my question. 12:57

6 A. That's fine. 12:57

7 Q. Are you aware -- do you know of any 12:57  
8 circumstances you haven't identified that you 12:57  
9 believe indicate adulterated Digitek made it to 12:57  
10 market? 12:57

11 A. You see, I still don't understand when 12:57  
12 you say "any and all" and "aware." The documents 12:57  
13 I've reviewed, that I was told to review and, you 12:57  
14 know, looked at and reviewed are the ones that 12:57  
15 I've built my report off of, and that's the 12:57  
16 circumstances where I found it. 12:57

17 I can't make a statement as broad as aware or 12:57  
18 whatever because there may be others out there. I 12:57  
19 don't know. 12:57

20 Q. You can't tell me what you know? 12:57

21 A. I'm telling you -- 12:57

22 Q. My question -- 12:57

23 A. -- what I know based on this, sir. 12:57

24 Q. My question was do you know of any other 12:57  
25 circumstances? 12:57

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1 A. Not to the documents I've reviewed. 12:57

2 Q. Dr. Bliesner, do you know of any other 12:57

3 circumstances that indicate defective Digitek -- 12:57

4 adulterated -- let me ask this correctly. 12:58

5 Do you know, do you have knowledge from any 12:58

6 source other than those that you've identified? 12:58

7 A. Other than those that I've reviewed. 12:58

8 Q. No. Other than that you've identified, 12:58

9 do you personally have knowledge as we sit here 12:58

10 today of any circumstances indicating adulterated 12:58

11 Digitek made it to market other than those you've 12:58

12 identified? 12:58

13 A. The two references, no. 12:58

14 Q. Other than those you've identified, 12:58

15 you're not aware of any other circumstances 12:58

16 indicating that defective -- I keep saying that -- 12:58

17 that adulterated Digitek was released to market; 12:58

18 is that correct? 12:58

19 A. To this point, no, that is correct. 12:58

20 MR. ANDERTON: Okay. I want this to be 12:58

21 clear. You keep injecting all this extra 12:58

22 stuff. So, Phil, I'm going to ask you to read 12:58

23 my last question back and I want you to answer 12:58

24 it very clearly, okay, without injecting all 12:59

25 kinds of additional stuff. 12:59

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1 THE WITNESS: I don't understand when you 12:59  
2 say "injecting." 12:59  
3 MR. ANDERTON: You think because of your 12:59  
4 prep sessions with counsel that you're 12:59  
5 absolutely required to qualify everything you 12:59  
6 say to leave doors open, as your notes say. 12:59  
7 This is a concise -- 12:59  
8 THE WITNESS: That's not true. 12:59  
9 MR. ANDERTON: It's absolutely true. 12:59  
10 THE WITNESS: It is not true. 12:59  
11 MR. ANDERTON: You wait till you watch 12:59  
12 the video. This is a very concise, very 12:59  
13 direct question. Phil, would you read it 12:59  
14 back? 12:59  
15 (Whereupon, the testimony was read 12:59  
16 back by the court reporter, as recorded above) 12:59  
17 THE WITNESS: Other than what I've 12:59  
18 reviewed -- which you state in there -- no. 01:00  
19 BY MR. ANDERTON: 01:00  
20 Q. Other than what you've identified. Stop 01:00  
21 injecting what you've reviewed into this. I'm 01:00  
22 asking you what you know, Dr. Bliesner. And we're 01:00  
23 going to ask this for hours until you answer my 01:00  
24 question. 01:00  
25 You have identified certain circumstances that 01:00

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1 you believe indicate adulterated Digitek was 01:00

2 released to market; is that correct? 01:00

3 A. Yes, yes. 01:00

4 Q. Other than the ones you've identified, 01:00

5 are you aware of any other circumstances that you 01:00

6 believe indicate adulterated Digitek was released 01:00

7 to market? 01:00

8 A. No. 01:00

9 Q. Thank you. 01:00

10 So what we have haven't discussed then is the 01:00

11 single tablet that is referenced in -- can you 01:00

12 turn to your report at page 87. Let me know when 01:00

13 you are there. 01:01

14 A. I am on page 87, sir. 01:01

15 Q. All right. Do you see paragraphs 46 and 01:01

16 49? 01:01

17 A. 46, yes. 01:01

18 Q. Okay. 01:01

19 A. 49, yes. 01:01

20 Q. All right. So to be clear, we talked 01:01

21 about the 1990 circumstances and we now know that 01:01

22 that had nothing to do with Digitek; right? 01:01

23 A. Most likely no. 01:01

24 Q. We talked about the 2004 circumstances 01:01

25 and we now know that that was not product that was 01:01

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1 part of the Digitek recall; right? 01:01

2 A. That is correct. 01:01

3 Q. And we talked about -- or we talked 01:01

4 about the 2008 batch 80228, which is part of 01:01

5 paragraph 47 here, and we know that because that 01:02

6 batch was rejected, it also doesn't show anything 01:02

7 about product making it to market. 01:02

8 A. With that batch, no. 01:02

9 Q. Correct? 01:02

10 A. Yes. 01:02

11 Q. Talking only about that paragraph, 01:02

12 Dr. Bliesner. 01:02

13 A. Okay, okay. 01:02

14 Q. Part of the issue here is that 01:02

15 Plaintiffs' lawyers have told you never to trust a 01:02

16 single word that comes out of my mouth, so... 01:02

17 A. That's not true. They've never made a 01:02

18 statement even remotely related to that. 01:02

19 Q. Do you want me to find it in your 01:02

20 notes? 01:02

21 Dr. Bliesner, what do you know about the 01:02

22 circumstances referred to in paragraphs 46 and 49 01:02

23 from memory? 01:02

24 A. From memory, I couldn't tell you whether 01:03

25 they were e-mails or they were reports. That's 01:03

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1 what I can tell you from memory. 01:03

2 Q. Okay. And does that mean that you also 01:03

3 don't remember the -- kind of the underlying 01:03

4 circumstances, regardless of whether you remember 01:03

5 the source? 01:03

6 A. Underlying circumstances? 01:03

7 Q. Yeah. 01:03

8 A. 46 and 49? 01:03

9 Q. Yeah. 01:03

10 A. No, I'd have to go back and look at the 01:03

11 records. 01:03

12 MR. ANDERTON: All right. Well, just 01:03

13 give me one moment. Let's go off the record 01:03

14 for a minute. 01:04

15 THE VIDEOGRAPHER: The time is now 01:04

16 1:03 p.m. We're going off the record briefly. 01:04

17 (Short break) 01:06

18 THE VIDEOGRAPHER: The time is now 01:06

19 1:06 p.m. We are back on the record. 01:06

20 BY MR. ANDERTON: 01:06

21 Q. Dr. Bliesner, I'm handing you a document 01:06

22 that has been marked as Exhibit 59A. Just take a 01:06

23 moment and look at that document, please. 01:06

24 A. Sure. It trails off. It's not a 01:06

25 complete -- 01:09

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1 Q. I understand. 01:09

2 A. Okay. 01:09

3 Q. Have you seen that document before? 01:09

4 A. I believe I have, yes. 01:09

5 Q. Okay. Turn to page 60 of your report, 01:09

6 please. 01:09

7 A. Okay. 01:09

8 Q. In fact this document is what you list 01:09

9 as your reference A58; isn't that right? 01:09

10 A. No. 01:10

11 Q. No? 01:10

12 A. It's got a different control number on 01:10

13 it than the one that I referenced, according to my 01:10

14 report. This is Mylan 000932683. 01:10

15 Q. Look at the next page, Doctor. 01:10

16 A. Okay. There we go. 01:10

17 Q. So there's an extra page on our Exhibit 01:10

18 59A about, but what you refer to as A58, the 01:10

19 precise page is exactly your -- is the second page 01:10

20 of our 59A; is that correct? 01:10

21 A. It looks like it. 01:10

22 Q. And are you -- do you have any reason to 01:10

23 believe that the -- 01:10

24 A. Excuse me for just a second. Yes. It's 01:10

25 the same, yes. 01:11

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1 Q. All right. So this is an e-mail thread 01:11  
2 between somebody at Mylan and somebody with an 01:11  
3 e-mail extension indicated as goldenliving.com, 01:11  
4 correct? 01:11  
5 A. At the top level, yes. 01:11  
6 Q. What's goldenliving.com, do you know? 01:11  
7 A. I have no idea. 01:11  
8 Q. Is it a pharmacist? 01:11  
9 A. I have no idea. 01:11  
10 Q. Yet on page 87 you characterize this as 01:11  
11 a pharmacist identifying a double-thick product 01:11  
12 from the marketplace; right? 01:11  
13 A. I say that based on the -- Pharm America 01:11  
14 brought the statement in here, so... 01:11  
15 Q. Is Pharm America a pharmacist? 01:11  
16 A. I couldn't say for sure. 01:11  
17 Q. You don't know? 01:11  
18 A. No. 01:12  
19 Q. And you don't know if golden living is a 01:12  
20 pharmacist? 01:12  
21 A. I could not say, no. 01:12  
22 Q. Okay. But you were happy to write in 01:12  
23 your report that Mylan acknowledged a pharmacist 01:12  
24 identifying a double-thick product in the market; 01:12  
25 right? Look at page 87 of the report. 01:12



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1 A. Yes, yes. Thank you. I do use the word 01:12  
2 pharmacist. And based on this e-mail alone, I 01:12  
3 couldn't definitively say in fact that was a 01:12  
4 pharmacist. 01:12

5 Q. Okay. So that doesn't appear to be an 01:12  
6 accurate characterization in your paragraph 49, 01:12  
7 does it? 01:12

8 A. I'm sorry? 01:12

9 Q. It doesn't appear to be an accurate 01:12  
10 characterization in your 49, does it? 01:13

11 A. It does not appear -- 01:13

12 Q. Okay. 01:13

13 A. -- to be. I'm sorry. I heard 01:13  
14 inaccurate, so. 01:13

15 Q. Well, I didn't say inaccurate. I said 01:13  
16 "an accurate," and I apologize if I spoke too 01:13  
17 quickly. 01:13

18 Turn to then the page that you actually refer 01:13  
19 to as A58. Now, is this the -- am I correct that 01:13  
20 this document is the basis for your concluding 01:13  
21 that adulterated Digitek that was part of the 01:13  
22 recall made it to market? 01:13

23 A. One of the two. 01:13

24 Q. What's the other one? 01:13

25 A. The other one was the pharmacist found a 01:13

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1 double-thick tablet, 47, what we talked about. 01:13

2 Q. But we know that wasn't part of the 2008 01:13

3 recall. 01:13

4 A. No, it was not part of the recall. 01:13

5 Q. All right. So this is the sole piece of 01:13

6 information that you have that provides any 01:13

7 indication that adulterated Digitek that was part 01:13

8 of the 2008 recall made it to market. 01:13

9 A. This is the only document I have 01:14

10 reviewed thus far, that... 01:14

11 Q. You're not aware of anything else. 01:14

12 You're not aware of any other document. 01:14

13 A. I have not reviewed any documents. 01:14

14 Q. That say that; right? 01:14

15 A. No. 01:14

16 Q. Okay. Let's look at this. 01:14

17 A. Uh-huh. 01:14

18 Q. Particularly the page -- and we touched 01:14

19 on this a little bit last time, but I want to talk 01:14

20 about it a little bit more thoroughly; okay? 01:14

21 A. Sure. 01:14

22 Q. A card of Digoxin with one 01:14

23 double-thickness tablet. 01:14

24 A. Uh-huh. 01:14

25 Q. So it's in a blister pack; right? 01:14

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1 A. I assume that's what the card is. 01:14

2 Q. Are you an expert on blister packs? 01:14

3 A. No. 01:14

4 Q. Packaging? 01:14

5 A. Packaging, no. 01:14

6 Q. Okay. Do you know whether this blister 01:14

7 pack was opaque on one side, like a lot of them 01:14

8 are? 01:14

9 A. I've never seen a description of a 01:14

10 blister pack with respect to this. 01:14

11 Q. You don't know anything about this 01:14

12 blister pack. 01:14

13 A. This one here? 01:14

14 Q. Yeah? 01:14

15 A. I -- there's not enough information to 01:14

16 say. 01:14

17 Q. Okay. And you don't know -- well, we 01:14

18 know that the tablet wasn't taken out of the 01:14

19 blister pack and measured, don't we? 01:15

20 A. This particular one? 01:15

21 Q. Yeah. 01:15

22 A. It says please advise that -- and, 01:15

23 again, I'm just -- this is all data we got here. 01:15

24 Q. I understand. 01:15

25 A. "Please be advised that Lynn Carol, CSC, 01:15

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1 reports finding a card of Digoxin with one double 01:15  
2 thickness tablet at GL" Gloucester. Whatever GL 01:15  
3 is. I guess maybe that's their -- 01:15

4 Q. An acronym for -- I can never say that. 01:15  
5 Gloucester? 01:15

6 A. Gloucester, yeah. "The card has four 01:15  
7 tablets remaining, one of which she reported was 01:15  
8 obviously double-thick." 01:15

9 So there were four tablets remaining in the 01:15  
10 blister pack, one of which was identified as 01:15  
11 double-thick. 01:15

12 Q. Which she believed was double-thick. 01:15

13 A. She believed was double-thick, yes. 01:15

14 Q. Did you do anything to try to verify 01:15  
15 whether this report was accurate or could be 01:15  
16 accurate? 01:16

17 A. No. 01:16

18 Q. You just accepted it at face value? 01:16

19 A. I accepted it as data that supported 01:16  
20 double packaging. 01:16

21 Q. At face value? 01:16

22 A. Yes, sir. 01:16

23 Q. You get paid for your analytical skills; 01:16  
24 right? 01:16

25 A. I do, sir. 01:16

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1 Q. And you hold yourself out to out as an 01:16  
2 individual possessing a high level of analytical 01:16  
3 skills; correct? 01:16

4 A. I would say that's a fair assessment. 01:16

5 Q. 550 an hour, that's a pretty talented 01:16  
6 analysis I would hope. And yet you didn't feel 01:16  
7 like this warranted any further analysis? 01:16

8 A. I don't think that's a fair statement. 01:16

9 Q. You didn't do any further analysis. 01:16

10 A. I didn't have -- first of all, I was 01:16  
11 asked to review certain sets of documents -- 01:17

12 Q. Right. 01:17

13 A. -- that were available to me at that 01:17  
14 time. 01:17

15 Q. Right. 01:17

16 A. And I reviewed those documents and 01:17  
17 extracted out of, you know, the thousands of pages 01:17  
18 that I reviewed, those things that were 01:17  
19 pertinent. I identified, as you saw, that lended 01:17  
20 support to the fact that there were difficulties. 01:17

21 Q. Okay. 01:17

22 A. And by the time that rolled around, 01:17  
23 there was no additional time to do any more 01:17  
24 detailed investigation other than what I had 01:17  
25 looked at. 01:17

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1 Q. Well, in fact -- and so you didn't do 01:17  
2 any more detailed investigation other than looking 01:17  
3 it with the Plaintiffs' attorneys. 01:17

4 A. With respect to this particular case? 01:17

5 Q. Right. 01:17

6 A. No. 01:17

7 Q. Well, but you actually reviewed a 01:17  
8 document that directly refutes the possibility of 01:17  
9 this being accurate, didn't you? 01:17

10 A. What was that? 01:17

11 Q. I mean you certainly wouldn't have 01:17  
12 ignored information that made it clear that this 01:17  
13 woman couldn't be correct, would you? 01:17

14 A. I'm sorry. I didn't understand that 01:17  
15 statement. 01:17

16 Q. If you had seen information that made it 01:17  
17 clear that this report couldn't be correct, you 01:18  
18 wouldn't have ignored that, would you? 01:18

19 A. If I had seen information that 01:18  
20 corroborated that? 01:18

21 Q. No, that contradicted it and made it 01:18  
22 very clear that this observation couldn't be 01:18  
23 correct, you wouldn't have ignored that, would 01:18  
24 you? 01:18

25 A. Oh, absolutely not, no. 01:18

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1 Q. I wouldn't think so. Not for 550 an 01:18

2 hour. 01:18

3 Dr. Bliesner, I'm going to hand you a document 01:18

4 that has been marked as Defendant's Exhibit 73, 01:18

5 although it doesn't have a sticker on it. 01:18

6 A. Okay. 01:18

7 Q. Phil, would you mind putting a sticker 01:18

8 on this one? Just says Exhibit 73. 01:18

9 Have you seen that -- well, Dr. Bliesner, take 01:19

10 a moment to look at that document, please. 01:19

11 A. Uh-huh. 01:19

12 Q. Have you reviewed Exhibit 73? 01:23

13 A. I have, sir. 01:23

14 Q. Have you see that document before? 01:23

15 A. That's a good question. 01:23

16 Q. Well, why don't you turn to page 47 of 01:23

17 your report. 01:23

18 A. Okay. 01:23

19 Q. We'll make short work of that good 01:23

20 question. 01:23

21 A. Okay. 01:23

22 Q. And for the record, that's two today. 01:23

23 A. I'm sorry? 01:23

24 Q. That's two good questions today. 01:23

25 Are you on page 47? 01:23

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1	A.	I am.	01:23
2	Q.	Do you see Exhibit -- or reference A36?	01:23
3	A.	I do.	01:23
4	Q.	Do you see that you described that as	01:23
5		being Plaintiffs' Exhibit M69?	01:23
6	A.	I do.	01:23
7	Q.	Do you see the front of our Exhibit 63,	01:23
8		indicating that that's M69?	01:23
9	A.	It is.	01:23
10	Q.	And you see that that is a UDL internal	01:23
11		investigation record?	01:23
12	A.	Yes.	01:23
13	Q.	From Digitek tablets? So what you're	01:23
14		looking at as Defendant's 73 --	01:23
15	A.	Yes.	01:23
16	Q.	-- is in fact your A36 reference;	01:23
17		correct?	01:23
18	A.	Yes.	01:23
19	Q.	So you looked at this document?	01:23
20	A.	Yes, sir.	01:24
21	Q.	In fact you made a point of highlighting	01:24
22		in your report information which you thought was	01:24
23		negative and adverse with respect to Activis. You	01:24
24		made a point of indicating that there was a	01:24
25		complaint about some tablets; right?	01:24



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1 A. Yes. 01:24

2 Q. Can you turn to page 2 of Exhibit 73? 01:24

3 A. Yes. 01:24

4 Q. Do you see the heading that says 01:24

5 "Examination of Retained Samples"? 01:24

6 A. Yes. 01:24

7 Q. Read that paragraph please for me out 01:24

8 loud. 01:24

9 A. Sure. "Examination of retained 01:24

10 samples. On 4/3/08, a visual examination of 01:24

11 retains for both strengths of Digitek were 01:24

12 completed. Upon evaluating the fit of the tablets 01:24

13 within the blister cavity, it was observed that 01:24

14 both blister cavity sizes have minimal head space 01:24

15 that would prevent tablets to be packaged with 01:25

16 double the thickness. If the tablet thickness 01:25

17 were to exceed the blister cavity size during 01:25

18 packaging, visible damage to the blister package 01:25

19 would occur and the -- excuse me -- the equipment 01:25

20 would experience a seal station overload, jamming 01:25

21 within the seal station, that would result in a 01:25

22 shutdown of the equipment. 01:25

23 This type of occurrence is documented on the 01:25

24 inspection record and the batch record. As stated 01:25

25 above, there is no documentation in the batch 01:25

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1 record of a machine- or inspection-related issues 01:25

2 involving tablet thickness." 01:25

3 Q. Did you read that document before you 01:25

4 prepared your report. You obviously did; right? 01:25

5 A. Yes sir. 01:25

6 Q. You read that language? 01:25

7 A. Yes, sir. 01:25

8 Q. It makes it clear that the woman who 01:25

9 thought she saw a double-thick tablet in a blister 01:25

10 pack couldn't have been correct, doesn't it? 01:25

11 A. I don't think you can say that 01:25

12 definitively. This is an internal investigation 01:25

13 report. This is what they report. There's -- 01:25

14 it's opinion based on their experience and 01:25

15 observation. 01:26

16 Q. But it's not opinion. It's a very 01:26

17 specific statement about the technical 01:26

18 specifications and capabilities of their packaging 01:26

19 equipment, isn't it? 01:26

20 A. Perhaps. 01:26

21 Q. What do you mean "perhaps"? 01:26

22 A. It's an investigation summary. 01:26

23 Investigation summaries don't necessarily report 01:26

24 all of the information in an accurate fashion on 01:26

25 what happened in the investigation. 01:26

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1 Q. Do you have any reason to believe that 01:26  
2 the information in this paragraph that you just 01:26  
3 read is inaccurate? 01:26

4 A. Any reason? 01:26

5 Q. Yes. 01:26

6 A. Based on my experience, unless I 01:26  
7 actually review an investigation report, I always 01:26  
8 wonder if the summary is -- how accurate it is, 01:26  
9 based on my experience. 01:26

10 Q. Do you have any reason to believe that 01:26  
11 this paragraph and the information in this 01:26  
12 paragraph is inaccurate? 01:26

13 A. Based on the comment from the person who 01:26  
14 saw it, I would say that there was a possibility 01:26  
15 that there was a double-thick tablet in that 01:26  
16 blister pack. 01:27

17 Q. So you're going to reject the 01:27  
18 information of the packaging entity that says 01:27  
19 their equipment would not allow packaging of 01:27  
20 double-thick tablet in favor of an unreliable, 01:27  
21 uncorroborated, unverified account of a woman in a 01:27  
22 nursing home that you characterized as a 01:27  
23 pharmacist. 01:27

24 MR. KERENSKY: Excuse me. Form. 01:27

25 BY MR. ANDERTON: 01:27

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1 Q. Is that what you're going to do? 01:27

2 A. What was his question. I'm sorry. 01:27

3 Q. His question was form. That means you 01:27

4 get to answer my question. Phil, would you please 01:27

5 read that back. 01:27

6 MR. KERENSKY: That's correct. 01:27

7 (Whereupon, the testimony was read 01:28

8 back by the court reporter, as recorded above) 01:28

9 THE WITNESS: Okay. 01:28

10 I am not rejecting this information. 01:28

11 It's part of the data. As far as the 01:28

12 characterization of a pharmacist, I don't have 01:28

13 any way to prove in fact it was a pharmacist 01:28

14 the way it's written in there. So this is 01:28

15 just additional data to -- that was discovered 01:28

16 during my review. 01:28

17 BY MR. ANDERTON: 01:28

18 Q. You have given sworn testimony today -- 01:28

19 A. Yes. 01:28

20 Q. -- that her report, the information in 01:28

21 our Exhibit 59A allows you to say we know 01:29

22 adulterated Digitek was released to market. 01:29

23 That's your sworn testimony. 01:29

24 A. My sworn testimony is we know that 01:29

25 there -- based on that pharmacist report in 01:29

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1 Bellingham, Washington, that that is true. 01:29

2 Q. Dr. Bliesner? 01:29

3 A. Yes, sir. 01:29

4 Q. I'm talking strictly about this 2008 01:29

5 situation and I want you to stay focused on that 01:29

6 for me; okay? 01:29

7 A. Okay. 01:29

8 Q. You've given sworn testimony here today 01:29

9 that says that this report of the woman who works 01:29

10 for goldenliving.com is the evidence that allows 01:29

11 you to conclude in your expert witness report that 01:29

12 you know adulterated Digitek that was part of the 01:29

13 recall -- 01:29

14 A. That's -- 01:29

15 Q. -- made it to market. 01:30

16 A. That's -- that's a misunderstanding of 01:30

17 what I said. We know that adulterated Digitek 01:30

18 made it to market because of the pharmacist's 01:30

19 discovery here. I have not definitively made a 01:30

20 statement this is a piece of evidence that 01:30

21 somebody potentially found a double-thick tablet 01:30

22 in the market characterized as a pharmacist. 01:30

23 Q. So then if I understand what you're 01:30

24 doing right now, Dr. Bliesner, you're backing away 01:30

25 from this report. 01:30

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1	A.	No, I'm not backing away.	01:30
2	Q.	Let's get it clear.	01:30
3	A.	Okay.	01:30
4	Q.	Does this -- do you believe this allows	01:30
5		to you conclude that --	01:30
6	A.	With the recalled lot?	01:30
7	Q.	That part that of -- that -- I'm talking	01:30
8		only about this situation.	01:30
9	A.	Okay.	01:30
10	Q.	Do not --	01:30
11	A.	That situation.	01:30
12	Q.	Do not inject any additional	01:30
13		circumstances into your answer; okay?	01:30
14	A.	Okay.	01:30
15	Q.	Are we clear on that?	01:30
16	A.	Yes, sir.	01:30
17	Q.	Are you sure?	01:31
18	A.	Yes, sir.	01:31
19	Q.	I'm talking about this report that is in	01:31
20		Defense Exhibit 59A.	01:31
21	A.	Yes.	01:31
22	Q.	Do you conclude from this report that	01:31
23		adulterated Digitek made it to market?	01:31
24	A.	Based on that one report and the fact	01:31
25		that I may have mischaracterized them as a	01:31

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1 pharmacist, I can't come to a firm conclusion on 01:31  
2 that. 01:31  
3 Q. You can't come to a firm conclusion on 01:31  
4 that? 01:31  
5 A. That's correct. 01:31  
6 Q. So when you said earlier -- 01:31  
7 A. Uh-huh. 01:31  
8 Q. -- we know -- 01:31  
9 A. Yes. 01:31  
10 Q. -- which is definitive. Am I correct -- 01:31  
11 A. Yes. 01:31  
12 Q. -- that adulterated Digitek was released 01:31  
13 to market, the only thing you have to support that 01:31  
14 definitive statement is the 2004 circumstances? 01:31  
15 A. In the documents I have already 01:31  
16 reviewed; correct. 01:31  
17 Q. Okay. The only thing you're aware of -- 01:31  
18 no matter what you've reviewed -- is the 2004 01:31  
19 circumstances; correct? 01:31  
20 A. That's the specific one, yes. 01:32  
21 THE WITNESS: I hate to do this to you. 01:32  
22 I need a bathroom break. 01:32  
23 MR. ANDERTON: You certainly may. 01:32  
24 THE VIDEOGRAPHER: The time is 1:31 p.m. 01:32  
25 We're going off the record briefly. 01:32

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1	(Short break)	01:40
2	THE VIDEOGRAPHER: The time is 1:42 p.m.	01:40
3	We're back on the record.	01:40
4	BY MR. ANDERTON:	01:40
5	Q. Dr. Bliesner, you just took a break.	01:40
6	Did you speak with Mr. Kerensky during that break?	01:40
7	A. Yes, I did.	01:40
8	Q. Who called who?	01:40
9	A. He called me.	01:40
10	Q. He did?	01:40
11	A. Yes.	01:40
12	Q. What did you talk about?	01:40
13	A. He wanted to ask me how I felt things	01:40
14	were going, how I felt.	01:41
15	Q. What did you tell him?	01:41
16	A. I said it's tiring, hard work. I didn't	01:41
17	get to the point where I said I don't know how you	01:41
18	people do this for a living, but that's what I was	01:41
19	thinking then he offered some advice.	01:41
20	Q. What was his advice?	01:41
21	A. His advice was you realize the report	01:41
22	that you wrote is not based on just one or two	01:41
23	observations of the adulterated product in the	01:41
24	market. The basis -- the majority of the basis of	01:41
25	the report is this total lack of compliance over	01:41



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1 the course of years. I said okay. 01:41

2 Q. Okay. So he told you to say that? 01:41

3 A. No, he didn't tell me to say that. He 01:41

4 said just remember. 01:41

5 Q. That's his words though, not yours. 01:41

6 A. No, it's -- yeah it's his words in 01:41

7 general. 01:41

8 Q. His words? 01:41

9 A. Yeah. But it is the basis of the 01:41

10 report. It's true. That's how it was written. 01:41

11 Q. But let's call that what it is. 01:41

12 A. Uh-huh. 01:41

13 Q. The basis of the report is inferences; 01:41

14 right? 01:41

15 A. Inferences? 01:41

16 Q. Sure. 01:41

17 A. How are you defining inferences? 01:41

18 Q. Well, you have either direct proof -- 01:42

19 A. Uh-huh. 01:42

20 Q. -- or inferential proof. You understand 01:42

21 the difference between the two; right? 01:42

22 A. I do not. 01:42

23 Q. Direct proof is something that proves a 01:42

24 proposition to be true. Something follows -- A 01:42

25 follows from B. 01:42

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1 A. Okay. 01:42

2 Q. Inferential proof is something that 01:42

3 doesn't necessarily prove something is true but 01:42

4 suggests it's true. 01:42

5 Do you understand the difference? 01:42

6 A. I think in those terms, yes. 01:42

7 Q. You know what an inference is; right? 01:42

8 A. Yes. 01:42

9 Q. You know what I mean? Dr. Bliesner, I'm 01:42

10 a little bit befuddled by your claimed lack of 01:42

11 understanding of some of these very basic terms 01:42

12 when you spend your life charging people \$500 an 01:42

13 hour or more to do highly technical analytical -- 01:42

14 to provide highly technical analytical services. 01:43

15 How do you not know the difference off the top of 01:43

16 your head between direct and inferential? 01:43

17 MR. KERENSKY: Objection, form. 01:43

18 BY MR. ANDERTON: 01:43

19 Q. You may answer. 01:43

20 A. I never been in a deposition with the 01:43

21 legal implication of some words. It's like the 01:43

22 definition of "is," is with Clinton. 01:43

23 Q. Do you know the difference between 01:43

24 direct proof and inferential proof in the ordinary 01:43

25 course of your FDA GMP consulting career? 01:43

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1 A. We never use the term infer. 01:43

2 Q. Okay. You've got -- 01:43

3 A. In my experience. 01:43

4 Q. So your conclusion in your report which 01:43

5 is set forth at page 21, you say it is my opinion 01:43

6 to a reasonable degree of certainty that the 01:44

7 systemic failure to implement quality systems and 01:44

8 to comply with regulations -- with the 01:44

9 regulations -- resulted in adulterated drug 01:44

10 products making it to the marketplace. 01:44

11 Did I read that correctly? 01:44

12 A. Yes, you did. 01:44

13 Q. As concerns the product, the Digitek 01:44

14 product that was part of the recall, you don't 01:44

15 have any direct proof of that, do you? 01:44

16 A. I have proof that they were in 01:44

17 substantial state of discompliance and that those 01:44

18 tablets were manufactured under the quality 01:44

19 systems or lack of quality systems therein and 01:45

20 therefore were at risk. 01:45

21 Q. So what you have proof of is the 01:45

22 possibility that adulterated Digitek was 01:45

23 manufactured; correct? 01:45

24 A. The likelihood that it could have been 01:45

25 manufactured. 01:45

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1 Q. Which is a possibility. 01:45

2 A. It's probable. 01:45

3 Q. Oh, now you know the difference between 01:45

4 possibility and probability. 01:45

5 A. We talked about it earlier today 01:45

6 remember? 01:45

7 Q. I see. You're a quick study. That's 01:45

8 good to know. 01:45

9 So in your mind it's probable but still you 01:45

10 have no proof; right? 01:45

11 A. With respect to the recalled lot? 01:45

12 Q. Correct. Lots. 01:45

13 A. Lots. 01:45

14 Q. Correct. With respect to the recalled 01:45

15 lots. 01:45

16 A. In what I've reviewed, no. 01:45

17 Q. All right. And so if you assert as a 01:45

18 conclusion that adulterated Digitek that was part 01:45

19 of the recalled lots made it to marketplace, the 01:46

20 only way you do that is by inference; right? 01:46

21 A. The only way? 01:46

22 Q. You don't have any direct proof. 01:46

23 A. For the recalled lots. 01:46

24 Q. Correct. And so the only way to reach 01:46

25 that conclusion is by inference; right? 01:46

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1 A. The chronic systemic failure of the 01:46  
2 quality system and the FDA actions, including two 01:46  
3 consent decrees and anything like that, if you're 01:46  
4 defining that as an inference, then the answer 01:46  
5 would be yes. 01:46

6 Q. Well, we know you didn't look at any 01:46  
7 Digitek production records; right? 01:46

8 A. That's not necessarily true. 01:46

9 Q. You looked at a portion of one batch 01:46  
10 record; right? 01:46

11 A. I can't remember specifically. I know I 01:46  
12 reviewed the ANDA that had batch records in it and 01:46  
13 I have probably read another document or two. 01:46

14 Q. Okay. There were 152 batches that were 01:46  
15 recalled. 01:47

16 A. Okay. 01:47

17 Q. You didn't review any of the batch 01:47  
18 records for those 152 batches except for a partial 01:47  
19 review of the batch where some double-thick 01:47  
20 tablets were found during manufacturing that were 01:47  
21 inspected out of the batch before it was 01:47  
22 released. And the only reason you read that is 01:47  
23 because you read the investigation report for that 01:47  
24 batch; correct? 01:47

25 A. I don't recall which batch record I 01:47

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1 looked at. I tell you that right now. 01:47

2 Q. Okay. You gave testimony about it last 01:47

3 time. 01:47

4 A. Okay. 01:47

5 Q. The record will show what it shows. 01:47

6 A. Okay. 01:47

7 Q. But you certainly didn't review any of 01:47

8 the batch records beyond that single batch with 01:47

9 respect to the recalled batches; correct? 01:47

10 A. I don't believe so. 01:47

11 Q. Okay. So you conducted a paper audit? 01:47

12 A. Yes, sir. 01:47

13 Q. Without reviewing production records? 01:47

14 A. Yes. 01:47

15 Q. And from that paper audit of 01:48

16 non-production records, primarily FDA regulatory 01:48

17 documentation, you conclude there is a possibility 01:48

18 that adulterated Digitek was produced and 01:48

19 therefore there is a possibility that adulterated 01:48

20 Digitek was released; correct? 01:48

21 A. No, it probably was released to market. 01:48

22 If you go back and you look at the FDA reports and 01:48

23 the findings, first of all, batch record is not 01:48

24 the end all be all for documenting whether things 01:48

25 are good or bad. In fact as we know from reading 01:48

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1 the documentation here is that there are numbers 01:48  
2 of people in the facility that don't even read 01:48  
3 English. So are they going to document anything 01:48  
4 bad on a batch record? It brings that into 01:48  
5 question. 01:48

6 So, you know, the reality is, is if people 01:49  
7 make mistakes and they don't read English, are 01:49  
8 they going to document them on a batch record? 01:49  
9 That's a good question and I can't answer it. But 01:49  
10 it brings into question the batch records doesn't 01:49  
11 necessarily show you anything definitive. 01:49

12 Q. You can't answer it because you didn't 01:49  
13 care enough to ask for or even attempt to review 01:49  
14 the batch records. You can't give any testimony 01:49  
15 about the information in the batch records for the 01:49  
16 recalled batches, can you? 01:49

17 A. In the batch records? 01:49

18 Q. Correct. 01:49

19 A. Again, I have to go back. But if I take 01:49  
20 you at your word, then -- and that from the 01:49  
21 previous testimony I reviewed a small portion of 01:49  
22 the batch record, then the answer is I reviewed a 01:49  
23 small portion of the batch record. 01:49

24 Q. From one lot. 01:49

25 A. If that's what's in the testimony 01:49

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1 previously, I'll say yes. 01:49

2 Q. And as concerns all of the other 151 01:49

3 lots at four-plus million tablets each that were 01:49

4 part of the recall, you can't give any testimony 01:49

5 about those batch records, can you? 01:50

6 A. Specifically the batch records? 01:50

7 Q. Yeah. 01:50

8 A. No. 01:50

9 Q. So you can't say anything one way or the 01:50

10 other about whether they're accurate not accurate, 01:50

11 whether there appears to be some sort of mistake 01:50

12 in them, you can't give any testimony about them, 01:50

13 can you? 01:50

14 A. That's not true. If you have a 01:50

15 substantial quality system failures as documented 01:50

16 by the FDA, you're going to have problems. 01:50

17 Q. How would the FDA determine whether a 01:50

18 quality system deficiency impacted a specific 01:50

19 product? How would the FDA do it? 01:50

20 A. How would they determine? 01:50

21 Q. Yeah. 01:50

22 A. They don't have to. They see quality 01:50

23 system failure, they write you up. 01:50

24 Q. They write you up. 01:50

25 How would they determine whether a specific 01:50



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1 product was impacted? 01:50

2 A. If it would not fall under the GMPs and 01:51

3 there was doubt, that's how they determine. 01:51

4 Q. That would create a possibility that 01:51

5 some deficiency impacted some product; right? 01:51

6 A. Say that again, or should I have him 01:51

7 read it back? Because I don't know if I 01:51

8 understand that. 01:51

9 MR. ANDERTON: Please, Phil, read it 01:51

10 back. 01:51

11 (Whereupon, the testimony was read 01:51

12 back by the court reporter, as recorded above) 01:51

13 THE WITNESS: Possibility that some 01:51

14 deficiency could potentially impact. The FDA 01:51

15 does not need the probable definition. All 01:51

16 they have to go in and see that there are 01:51

17 deficiencies with respect to the quality 01:51

18 systems. They do whatever they want and take 01:51

19 action on it. 01:51

20 BY MR. ANDERTON: 01:51

21 Q. I understand that. 01:51

22 A. Uh-huh. 01:51

23 Q. I asked you a question and I would like 01:51

24 you to answer now. How would the FDA determine 01:51

25 whether a specific GMP systems deficiency impacted 01:51

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1 a specific problem? I'm sorry a specific 01:52  
2 product. 01:52

3 A. Well, I don't work for the FDA and I'm 01:52  
4 not going to speak for the FDA, but if they 01:52  
5 find -- go back look at the EIRs and see that 01:52  
6 there are all kinds of problems with respect to 01:52  
7 manufacturing records and lack of manufacturing 01:52  
8 records, validated processes and things like 01:52  
9 that. So that's what they do. 01:52

10 They put -- if the question as to the 01:52  
11 integrity of the manufactured product, then, you 01:52  
12 know, they take action. 01:52

13 Q. What question were you just answering? 01:52  
14 I move to strike that as completely 01:52  
15 non-responsive. 01:52

16 Were you talking about Activis or their 01:52  
17 records somehow? 01:52

18 A. I'm talking about the records that the 01:52  
19 FDA reviewed and their systems and places that 01:52  
20 will show up on the establishment inspection 01:52  
21 report. 01:52

22 Q. Are you an expert in GMP compliance or 01:52  
23 not? 01:53

24 A. Am I am, sir. 01:53

25 Q. Okay. I'm asking you a question about 01:53

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1 FDA practice that ought to be right down the 01:53  
2 middle of that expertise. I don't know why you 01:53  
3 don't want to answer it, but -- I know exactly why 01:53  
4 you don't want to answer it but I'm going to keep 01:53  
5 asking it until you do. 01:53

6 MR. KERENSKY: Objection, form. 01:53

7 BY MR. ANDERTON: 01:53

8 Q. Okay. How would the FDA -- let's 01:53  
9 assume, Dr. Bliesner, that the FDA was doing an 01:53  
10 inspection and uncovered a GMP practice that they 01:53  
11 believed was deficient. 01:53

12 A. Okay. 01:53

13 Q. That happens; right? 01:53

14 A. Yes, it does. 01:53

15 Q. That's what you charge your clients to 01:53  
16 assess; right? 01:53

17 A. Yes. 01:53

18 Q. If the FDA wanted to determine whether 01:53  
19 that GMP deficiency impacted a particular product, 01:53  
20 how would they do that? 01:53

21 A. They may or may not start looking at all 01:54  
22 of the quality systems that are in there. I'm 01:54  
23 just telling you how they do it. They could stop 01:54  
24 when they see significant deficiencies and there 01:54  
25 is doubt in their mind they just stop. That's 01:54

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1 what they do. 01:54

2 Q. Why don't you want to ask answer that 01:54

3 question? I know the answer. I know why you 01:54

4 don't want to. 01:54

5 A. Well, what's the answer? 01:54

6 Q. Dr. Bliesner, how would the FDA 01:54

7 determine whether a specific GMP deficiency 01:54

8 impacted a specific product? What would they do? 01:54

9 MR. KERENSKY: Objection, form, prior to 01:54

10 the word "how?" 01:54

11 BY MR. ANDERTON: 01:54

12 Q. You may answer. 01:54

13 A. Again, please. 01:54

14 Q. I'll ask it again. 01:54

15 A. Okay. 01:54

16 Q. And we're going to set up the whole 01:54

17 situation again; okay? 01:54

18 A. Okay. 01:54

19 Q. So that I understand -- so that I know 01:54

20 you're clear in what we're talking about. 01:54

21 A. Okay. 01:55

22 Q. The FDA can -- the FDA conducts 01:55

23 inspections; right? 01:55

24 A. That's correct. 01:55

25 Q. If they notice a condition which they 01:55

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1 believe is a violation of good manufacturing 01:55  
2 practices -- 01:55  
3 A. Yes. 01:55  
4 Q. -- they make a note or a record of that 01:55  
5 somehow; correct? 01:55  
6 A. Yes, they do. 01:55  
7 Q. If that GMP violation or deficiency 01:55  
8 related to a specific -- or to a quality system, 01:55  
9 they'd make a note of that; right? 01:55  
10 A. Yes, they do 01:55  
11 Q. And they notify the company of that 01:55  
12 quality system GMP deficiency; right? 01:55  
13 A. Typically, yes. 01:55  
14 Q. All right. In the ordinary course, 01:55  
15 that's what they would do? 01:55  
16 A. Yes. 01:55  
17 Q. They are not in the business of ignoring 01:55  
18 or overlooking deficiencies that they find, are 01:55  
19 they? 01:55  
20 A. No, not at all. Not at all. 01:55  
21 Q. I don't know why you felt compelled to 01:55  
22 say typically in that situation. But Dr. Bliesner 01:55  
23 in that situation, if the FDA found a GMP 01:55  
24 deficiency in the quality systems and wanted then 01:56  
25 to inquire or determine whether that deficiency 01:56

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1 had any impact on a specific product -- 01:56

2 A. Yes. 01:56

3 Q. -- what would they do? 01:56

4 MR. KERENSKY: Form. Objection, form. 01:56

5 THE WITNESS: It depends, you know, what 01:56

6 deficiency it is in quality systems; all 01:56

7 right? For instance, let's say they go in the 01:56

8 laboratory, they pull up some data, they look 01:56

9 at chromatograms -- 01:56

10 BY MR. ANDERTON: 01:56

11 Q. Stop. Data and chromatograms for what? 01:56

12 For the product? 01:56

13 A. Yes. 01:56

14 Q. Sounds to me like they're reviewing 01:56

15 production records for that product. 01:56

16 A. They will review batch records as well. 01:56

17 Q. Okay. 01:56

18 A. Chromatographic data and reports aren't 01:56

19 necessarily -- you know, they're included with the 01:56

20 reported results, included in batch record, but 01:57

21 the raw data and the stuff is not. 01:57

22 Q. You don't think that's part of the batch 01:57

23 record? 01:57

24 A. The data is reported results, but 01:57

25 chromatograms in my experience traditionally are 01:57

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1 not. Electronic data are traditionally not. 01:57

2 Q. But the data is? 01:57

3 A. The final results. 01:57

4 Q. The data that the chromatogram generates 01:57

5 or reflects is part of the batch record; right? 01:57

6 A. We're talking about -- I'm -- please 01:57

7 don't take this wrong. Your understanding of raw 01:57

8 data as opposed to a result, they're different 01:57

9 things. 01:57

10 Q. Okay. 01:57

11 A. Okay. 01:57

12 Q. But the bottom line is the FDA if they 01:57

13 wanted to determine whether a quality systems 01:57

14 deficiency impacted a specific product, they'd go 01:57

15 look at the records, some portion of the records 01:57

16 for that specific product, wouldn't they? 01:57

17 A. They'll look at the records that 01:57

18 indicate where the difficulties are. For 01:57

19 instance, if they think there's problems with an 01:58

20 analytical method, they'll go in and they'll start 01:58

21 pulling up chromatographic data, look at the 01:58

22 results that come out there, look at peaks, look 01:58

23 how they're innovated, pull up the development 01:58

24 report, pull up the validation report, things like 01:58

25 that. 01:58

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1 If they think there are discrepancies with 01:58  
2 respect to improper documentation or execution of 01:58  
3 batch records, then they can pull the batch 01:58  
4 records and take a look at it. 01:58

5 Q. So what you've just described is a 01:58  
6 process whereby the FDA would look at some 01:58  
7 variation, some component -- some or all of the 01:58  
8 production records for the product. The only way 01:58  
9 they could conclude that a quality system 01:58  
10 deficiency actually impacted a specific product is 01:58  
11 to go look at the records that relate to that 01:58  
12 product; correct? 01:58

13 A. The raw data in the records, the reports 01:58  
14 that come out of it. 01:58

15 Q. Right. 01:58

16 A. That's correct. 01:58

17 Q. Couldn't reach that to product -- strike 01:58  
18 that. 01:58

19 MR. ANDERTON: We're going to change the 01:59  
20 tape. 01:59

21 THE VIDEOGRAPHER: It's 2:01 p.m. We're 01:59  
22 going off the record. 01:59

23 (Short break) 02:00

24 THE VIDEOGRAPHER: The time is 2:03 p.m. 02:00

25 We are back on record. This is the beginning 02:02



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1 of tape six. 02:02

2 BY MR. ANDERTON: 02:02

3 Q. Dr. Bliesner, in the paper audit that 02:02

4 you conducted, you placed heavy emphasis on the 02:02

5 FDA regulatory documents, didn't you? 02:02

6 A. Yes, sir, I did. 02:02

7 Q. They carry great weight with you, don't 02:02

8 they? 02:02

9 A. Yes, they do. 02:02

10 Q. Dr. Bliesner, I'm handing you a document 02:02

11 that has been marked as -- previously marked by 02:03

12 the Plaintiffs as Exhibit 68. As you can see by 02:03

13 the sticker, they used it in a deposition on 02:03

14 December 9, 2009. 02:03

15 A. Okay. 02:03

16 Q. Will you just look at that document for 02:03

17 a moment? I don't want you to read it. 02:03

18 A. Okay. 02:03

19 Q. I just want you to skim through it and 02:03

20 satisfy yourself of what it is. 02:03

21 MR. KERENSKY: I can't hear what 02:03

22 exhibit. I'm sorry. 02:03

23 MR. ANDERTON: 68, Mike. 02:03

24 MR. KERENSKY: Okay. 02:04

25 MR. ANDERTON: And it's Plaintiffs' 02:04

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1 Exhibit 68. You got that part; right? 02:04

2 MR. KERENSKY: I did not. Thank you. 02:04

3 That's why I couldn't find it. 02:04

4 MR. ANDERTON: Right. I'm here to help, 02:04

5 Mike. 02:04

6 BY MR. ANDERTON: 02:05

7 Q. Have you seen that document before? 02:05

8 A. I believe I have seen it either as part 02:05

9 of an EIR or stand-alone or both. 02:05

10 Q. I'll take that as a yes. It's a 2006 02:05

11 483 -- it's a 483 form issued in August of 2006 by 02:05

12 the FDA, following an inspection of the Activis 02:05

13 Totowa Little Falls facility; correct? 02:05

14 A. Yes. 02:05

15 Q. Dates of inspection July 10, 2006, to 02:05

16 August 10, 2006; correct? 02:05

17 A. Correct. 02:05

18 Q. All right. And are you familiar enough 02:05

19 with the document, Dr. Bliesner, to -- to say that 02:05

20 this document relates to various GMP circumstances 02:06

21 of Activis Totowa, as reflected in this inspection 02:06

22 report? 02:06

23 A. GMP circumstances? 02:06

24 Q. Yeah. 02:06

25 A. Failure of compliance? Failure of 02:06

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1 compliance I would say, yes. 02:06

2 Q. For GMP issues? 02:06

3 A. Yes. 02:06

4 Q. Look at page 5. 02:06

5 A. Uh-huh. 02:06

6 Q. Observation seven. Do you see that? 02:06

7 A. Yes. 02:06

8 Q. That is an observation that relates to 02:06

9 the bulk stability hold times studies. 02:06

10 Do you see that? 02:06

11 A. Yes. Just, if I may, I may not -- 02:06

12 Q. Dr. Bliesner. 02:06

13 A. -- have seen some of this stuff because 02:07

14 a lot of the copies we had were redacted, just so 02:07

15 you know. 02:07

16 Q. Well, nothing like hiding something from 02:07

17 yourself. 02:07

18 Well, let's just do it. You see observation 02:08

19 five on there or observation seven there on page 02:08

20 5? 02:08

21 A. Yes. 02:08

22 Q. All right. Do you remember the 02:08

23 testimony that you gave on January 25th about bulk 02:08

24 stability hold time studies? 02:08

25 A. No. 02:08

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1 Q. You don't; okay. 02:08

2 Do you remember telling Mr. Moriarty that you 02:08

3 questioned whether the Activis -- whether the 02:08

4 Digitek process validation -- whether the FDA had 02:08

5 any issues with the Digitek process validation 02:08

6 because you had seen a reference to bulk stability 02:08

7 hold times in this 483, and you thought that that 02:08

8 related to process validation? 02:08

9 A. I don't recall that, that statement. 02:08

10 Q. Do you -- do you -- 02:08

11 A. I -- 02:08

12 Q. -- stand by that testimony? Does bulk 02:08

13 stability hold time studies have anything to do 02:09

14 with process validation? 02:09

15 A. I'm not clear what they're meaning by 02:09

16 bulk stability hold here. 02:09

17 Q. You gave the testimony, Dr. Bliesner, I 02:09

18 didn't. I'm asking you a question. Does bulk 02:09

19 stability hold time studies have anything to do 02:09

20 with process validation? 02:09

21 MR. KERENSKY: Objection, form. 02:09

22 MR. ANDERTON: What's wrong with that 02:09

23 form, Mike? I would like to correct it if you 02:09

24 will allow. 02:09

25 MR. KERENSKY: It's a sidebar. You gave 02:09

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1 him the answer, I didn't. I doubt you will. 02:09

2 MR. ANDERTON: Say that one more time. 02:09

3 What's wrong with the form? 02:09

4 MR. KERENSKY: It is a sidebar of you 02:09

5 gave the testimony, I didn't. That kind of 02:09

6 comment prior to the question is objectionable 02:09

7 where I practice law. 02:09

8 MR. ANDERTON: Oh, okay. 02:09

9 BY MR. ANDERTON: 02:09

10 Q. So my question, Dr. Bliesner, absent any 02:09

11 preface comment is do bulk stability hold time 02:10

12 studies have anything to do with process 02:10

13 validation? 02:10

14 A. They can, yes. 02:10

15 Q. As you read this observation 7, does it? 02:10

16 A. With respect to these products. 02:10

17 Q. It does? 02:10

18 A. Bulk stability -- we're talking about 02:10

19 final blend or are we talking about manufactured 02:10

20 tablets? In this particular case it's 02:10

21 particularly clear. 02:10

22 Q. Okay. What's really clear, however -- 02:10

23 A. Uh-huh. 02:10

24 Q. -- is that Digitek -- 02:10

25 A. Uh-huh. 02:10

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1 Q. -- is not mentioned as one of the 02:10  
2 products that the FDA cited in this observation; 02:10  
3 correct? 02:10

4 A. In the copy I'm looking at, yes. 02:10

5 Q. Do you think that I'm looking at a 02:10  
6 different copy? 02:10

7 A. I was specifically told don't look at 02:10  
8 anything that has to do with any other product 02:10  
9 other than Digitek. So if I had this copy with no 02:10  
10 Digitek on there, I'm pretty sure I would not have 02:11  
11 made a comment on it. 02:11

12 Q. Well, Dr. Bliesner, again, the last time 02:11  
13 you were here -- 02:11

14 A. Okay. 02:11

15 Q. -- you identified this observation as a 02:11  
16 reason why you questioned the validity of the 02:11  
17 Digitek process validation. I'm sorry. Let me 02:11  
18 strike that. 02:11

19 You cited to this observation as a basis for 02:11  
20 wondering whether the FDA questioned the process 02:11  
21 validation for Digitek. So does this have 02:11  
22 anything to do with the process validation for 02:11  
23 Digitek? 02:11

24 A. In this particular case, it does not 02:11  
25 look so. 02:11

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1 Q. It does not? 02:11

2 A. Yes, uh-huh. 02:11

3 Q. Okay. Are you aware of any other 02:11

4 evidence that you have reviewed that calls into 02:11

5 question the validity of the Digitek process 02:11

6 validation? 02:12

7 A. Yes. 02:12

8 Q. What? 02:12

9 A. There were internal studies and 02:12

10 investigations with respect to process validation, 02:12

11 blend uniformity. 02:12

12 Q. Okay. So there were investigations -- 02:12

13 A. I misspoke. With respect to process 02:12

14 validation, no. 02:12

15 Q. Okay. 02:12

16 A. With respect to blend uniformity. I'm 02:12

17 sorry. 02:12

18 MR. ANDERTON: Phil, would you please 02:12

19 read back my question very slowly and very 02:12

20 deliberately. Dr. Bliesner, would you please 02:12

21 answer my question? 02:12

22 THE WITNESS: Yes, sir. 02:13

23 (Whereupon, the testimony was read 02:13

24 back by the court reporter, as recorded above) 02:13

25 THE WITNESS: I have to go back through 02:13

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1 my report and take a look. 02:13

2 BY MR. ANDERTON: 02:13

3 Q. You're really desperate not to do 02:13

4 anything you can to undermine Activis, aren't 02:13

5 you? You already testified about this last time, 02:13

6 Dr. Bliesner, and you identified only the bulk 02:13

7 stability hold time studies. 02:13

8 MR. KERENSKY: Form. 02:13

9 BY MR. ANDERTON: 02:13

10 Q. Now you have reviewed your report 02:13

11 forwards and backwards many times today and many 02:13

12 times last time. Are you aware -- 02:13

13 MR. KERENSKY: The witness is allowed to 02:13

14 review his report as much as he can to give 02:13

15 accurate testimony, and I think you probably 02:13

16 know that. 02:13

17 MR. ANDERTON: I do know that. I also 02:13

18 know that he's now contradicting his own prior 02:13

19 testimony whether he realizes it or not. So 02:13

20 if he wants to go back through his report, he 02:13

21 certainly may. 02:13

22 BY MR. ANDERTON: 02:14

23 Q. But my question is are you aware of any 02:14

24 other evidence that calls into question the 02:14

25 validity of the process validation for Digitek? 02:14



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1 A. Any other information? Again, I need to 02:14  
2 go back through my report and see what references 02:14  
3 I reviewed with respect to process validation. 02:14

4 Q. You didn't say anything about the 02:14  
5 Digitek process validation in your report, not a 02:14  
6 word about it being unreliable, and you testified 02:14  
7 last time that you didn't review the process 02:14  
8 validations. 02:14

9 Out of a desperate attempt to create some 02:14  
10 negative inference with respect to Activis, you 02:14  
11 tried to identify this bulk stability hold time 02:14  
12 reference in this 483 as evidence. 02:14

13 MR. KERENSKY: Is that a question or a 02:14  
14 speech? In either case, I object as to form. 02:14

15 BY MR. ANDERTON: 02:14

16 Q. So, Dr. Bliesner, what -- if you didn't 02:14  
17 say anything in your report about process 02:14  
18 validation, what would you be looking for? 02:15

19 MR. KERENSKY: Objection, form. Assumes 02:15  
20 facts not in evidence. 02:15

21 BY MR. ANDERTON: 02:15

22 Q. You may -- you may answer. 02:15

23 A. Ask it again, please. 02:15

24 Q. If you didn't say anything about the 02:15  
25 Digitek process validation in your report -- 02:15

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1 A. That's correct. 02:15

2 Q. -- what would you be looking for? 02:15

3 A. If I didn't? 02:15

4 Q. Yeah. 02:15

5 A. Chances are I didn't have documents that 02:15

6 would support that. 02:15

7 Q. So -- 02:15

8 A. Chances are. 02:15

9 Q. So you wouldn't have any evidence? 02:15

10 A. None of the documents were not given to 02:15

11 me to review. 02:15

12 Q. Oh, you assume they're out there, you 02:15

13 just didn't get them? 02:15

14 A. I know they're out there. 02:15

15 Q. You know there's documents out there 02:15

16 that call the process validation into question? 02:15

17 A. No, I don't have a question on the 02:15

18 documents with respect to process validation. 02:15

19 Q. And by the way, you most certainly were 02:15

20 given them if you reviewed all of Plaintiffs' 02:15

21 exhibits. 02:15

22 A. I did not review all of Plaintiffs' 02:15

23 Exhibits in detail. 02:15

24 Q. Didn't you tell me that last night from 02:15

25 Plaintiffs' counsel you received process 02:16

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1 validation? 02:16

2 A. Yes, and that's when I told you I got 02:16

3 that document last night and I didn't review it. 02:16

4 Q. Okay. 02:16

5 A. That's -- I got it late. 02:16

6 Q. Well, Dr. Bliesner, you've already given 02:16

7 this testimony last time. With respect to 02:16

8 observation 7 -- 02:16

9 A. Uh-huh. 02:16

10 Q. -- on the 2006, 483 -- 02:16

11 A. Uh-huh. 02:16

12 Q. -- does that have anything to do with 02:16

13 the Digitek process validation? 02:16

14 A. No, this is just related to these 02:16

15 products here. 02:16

16 Q. Okay. 02:16

17 A. According to this document. 02:16

18 Q. Can't resist, can you? 02:16

19 A. Resist what? I'm sorry. 02:16

20 Q. Your -- your solicited, gratuitous, 02:16

21 editorial comments at the end of every answer to 02:16

22 make sure you follow Plaintiffs' counsels' 02:16

23 directive to keep the door open. 02:16

24 MR. KERENSKY: Objection to form. You 02:16

25 know, speaking objections go for both sides of 02:16

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1 the table. 02:16

2 MR. ANDERTON: I'm sorry, Mike. I'm not 02:16

3 sure I understand. 02:17

4 MR. KERENSKY: You know when you give a 02:17

5 speech like that, admonishing the witness and 02:17

6 trying to intimidate the witness, that's just 02:17

7 like a speaking objection, trying to coach the 02:17

8 witness. 02:17

9 MR. ANDERTON: I'm merely trying to get 02:17

10 him to answer the questions that are asked of 02:17

11 him. We've been down this road all day. 02:17

12 MR. KERENSKY: I think you should stick 02:17

13 to questions and not speeches. 02:17

14 MR. ANDERTON: Okay. 02:17

15 MR. KERENSKY: Save speeches for the 02:17

16 judge and the jury would be my recommendation. 02:17

17 MR. ANDERTON: I appreciate your 02:17

18 recommendation, Mike. 02:17

19 MR. KERENSKY: Thank you. 02:17

20 BY MR. ANDERTON: 02:17

21 Q. So Dr. Bliesner, I'm now going to hand 02:17

22 you a document that has been marked as -- 02:17

23 previously marked as Plaintiffs' Exhibit 25. Take 02:17

24 a moment and look at that document, please. 02:17

25 Actually, may I see that back? 02:18

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1 A. Sure. 02:18

2 Q. I may have given you the wrong 02:18

3 document. No. 02:18

4 THE WITNESS: This is going to look like 02:18

5 delaying tactics, but I've got to go to the 02:18

6 bathroom. 02:18

7 MR. ANDERTON: Okay. 02:18

8 THE VIDEOGRAPHER: The time is 2:19 p.m. 02:18

9 We're going off the record. 02:18

10 (Short break) 02:25

11 THE VIDEOGRAPHER: The time is 2:27 p.m. 02:25

12 We are back on the record. 02:25

13 MR. ANDERTON: We're going to make a 02:25

14 record of that before we close down, Mike, if 02:25

15 that's all right. 02:25

16 MR. KERENSKY: Yes, that's fine. 02:25

17 BY MR. ANDERTON: 02:25

18 Q. Dr. Bliesner, I'm going to hand you what 02:25

19 has previously been marked as Plaintiffs' Exhibit 02:25

20 25. 02:25

21 A. Okay. 02:25

22 Q. Have you seen that document before? 02:25

23 A. I believe I have, but there was an 02:26

24 original one and there was a revised one, and I'm 02:26

25 not sure which one I had the ability to review. 02:26

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1 Q. You don't know whether you got to review 02:26  
2 the revised warning letter? If you don't know 02:26  
3 that, how do you know there was one? 02:26

4 A. There was -- if I recall, correctly 02:26  
5 there was a warning letter and then there was a 02:27  
6 revised warning letter. 02:27

7 Q. Yeah, what's this document say on top? 02:27

8 A. This one is the revised warning letter. 02:27  
9 I'm not sure which one I looked at. 02:27

10 Q. Did you only look at one of those two? 02:27

11 A. I don't recall. Let's see. 02:27

12 Q. All right. Dr. Bliesner, look at page 02:27  
13 41 of your report. 02:27

14 A. Okay. Okay. And that would be it? 02:27

15 Q. Have you seen that document before? 02:27

16 A. Yes. 02:27

17 Q. In fact you reviewed it preparing your 02:27  
18 report; right? 02:28

19 A. Yes. 02:28

20 Q. And according to your description of 02:28  
21 content, I'll use your words not mine, this 02:28  
22 warning letter -- this is -- starts on page 41 and 02:28  
23 continues on to page 42. 02:28

24 A. Yes. 02:28

25 Q. This warning letter is -- relates 02:28

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1 directly to the 483 that we discussed a moment 02:28  
2 ago, that is Plaintiffs' Exhibit 68; correct? 02:28  
3 A. I'm sorry. Say that again. I was 02:28  
4 looking at the contents. 02:28  
5 Q. This warning letter -- 02:28  
6 A. Yes. 02:28  
7 Q. -- relates directly to the 483 that is 02:28  
8 Plaintiffs' Exhibit 68; correct? 02:28  
9 A. I don't know. The warning letter? Yes. 02:28  
10 Q. Okay. So you have an inspection in July 02:28  
11 and August of 2006 resulting a 483; right? 02:28  
12 A. Uh-huh. 02:28  
13 Q. You have to say or no? 02:28  
14 A. Yes, I'm sorry. 02:29  
15 Q. About six months later, a warning letter 02:29  
16 was issued by the FDA; right? 02:29  
17 A. That's correct, uh-huh. 02:29  
18 Q. Okay. All right. Dr. Bliesner, I'm 02:29  
19 handing you a document that has been marked as 02:29  
20 Plaintiffs' Exhibit 171. 02:29  
21 A. Okay. 02:29  
22 Q. And this document was actually marked 02:29  
23 twice but go to page 44 of your report, please. 02:29  
24 A. I'm sorry 44 of the? 02:30  
25 Q. Of your report. 02:30

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1 A. My report; okay. A little punchy. 02:30  
2 Sorry. 02:30  
3 Q. Do you see reference A29? 02:30  
4 A. I do. 02:30  
5 Q. Is your reference A29 -- notwithstanding 02:30  
6 the discrepancy in the exhibit numbers as I told 02:30  
7 you, this document was marked twice at two 02:30  
8 depositions, one says 158, one says 171. 02:30  
9 Nevertheless, please look at your reference A29 02:30  
10 and tell me whether that is the same thing as what 02:30  
11 you've now been given, which is in front of you as 02:30  
12 Exhibit 171. 02:30  
13 A. A29. And your statement again was? 02:31  
14 Q. Is that the same as your reference A29? 02:31  
15 A. Let me double check. My A29 doesn't 02:31  
16 have the cover letter. 02:31  
17 Q. Doesn't have the cover letter, but 02:31  
18 otherwise is it the exact same EIR? 02:31  
19 A. It is, but there's redactions 02:32  
20 Q. In which one? 02:32  
21 A. This one you just handed me as opposed 02:32  
22 to this one. 02:32  
23 Q. Okay. 02:32  
24 A. So there -- 02:32  
25 Q. That's fine. 02:32



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1	A.	Uh-huh.	02:32
2	Q.	Now, let's look at -- and again working	02:32
3		from the one I handed you as 171.	02:32
4	A.	Okay.	02:32
5	Q.	Turn to page 11.	02:32
6	A.	11 of 40?	02:33
7	Q.	Correct.	02:33
8	A.	Okay.	02:33
9	Q.	Actually, let's go to page 2 of 40.	02:33
10		Do you see the summary?	02:33
11	A.	Yes, sir.	02:33
12	Q.	The first sentence of the summary	02:33
13		indicates that this inspection was conducted as a	02:33
14		follow-up to warning letter 07-NWJ-06.	02:33
15	A.	Okay.	02:33
16	Q.	Is that the same warning letter that is	02:33
17		Plaintiffs' Exhibit 25 that you just looked at a	02:33
18		moment ago?	02:33
19	A.	25 you said; correct?	02:33
20	Q.	Uh-huh.	02:34
21	A.	Okay. It does appear to be, yes.	02:34
22	Q.	Okay. Is it or not?	02:34
23	A.	Yes, according to the code, yeah.	02:34
24	Q.	Okay. And -- and so you know from your	02:34
25		experience that when a warning letter is issued	02:34

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1 oftentimes -- maybe not perhaps all of the time -- 02:34

2 the FDA will come back and ask to see verification 02:34

3 of remedial activities and corrective activities 02:34

4 performed by the manufacturer to the items set 02:34

5 forth in the warning letter; correct? 02:34

6 A. That is common, yes. 02:34

7 Q. Okay. You've assisted clients with -- 02:34

8 with exactly those types of inspections, haven't 02:34

9 you? 02:34

10 A. Inspections or the remediation. 02:34

11 Q. Well, remediation and then the follow-up 02:34

12 inspections. 02:34

13 A. Yes. 02:34

14 Q. You've assisted with both. 02:34

15 A. Yes. 02:34

16 Q. Right? 02:34

17 A. Yes. 02:34

18 Q. Okay. So this inspection then that was 02:34

19 conducted in 2007 -- 02:35

20 A. Okay. 02:35

21 Q. -- from September 5 to September 28 -- 02:35

22 do I have those dates right? 02:35

23 A. Yes. 02:35

24 Q. It was a follow-up inspection to the 02:35

25 warning letter that was -- the revised warning 02:35

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1 letter that was issued February 1, 2007, which was 02:35  
2 issued after an inspection in July and August of 02:35  
3 2006; correct? 02:35

4 A. The original inspection July, August, 02:35  
5 2006, yes. Follow-up inspection off the issued 02:35  
6 warning letter September, yes. 02:35

7 Q. Okay. 02:35

8 A. Uh-huh. 02:35

9 Q. So the items that are set forth in the 02:35  
10 warning letter -- 02:35

11 A. Uh-huh. 02:35

12 Q. -- of February 1, 2007 -- 02:35

13 A. Uh-huh. 02:35

14 Q. -- are the items that are also set forth 02:35  
15 in the 483 issued in August of 2006 following the 02:35  
16 inspection; right? 02:36

17 A. Correct. 02:36

18 Q. Now -- now we can go to -- well, 02:36  
19 actually go to page 5 of 60. 02:36

20 A. 5 of 60? 02:36

21 Q. On the EIR for the 2007 inspection. 02:36

22 A. Okay. 02:36

23 Q. Do you see the first paragraph there? 02:36

24 A. The compliance status? 02:36

25 Q. Yes. 02:36

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1 A. Yes. 02:36

2 Q. What's a compliance hold? 02:36

3 A. A compliance hold is where they may put 02:36

4 a hold on manufacturing and shipping of certain 02:36

5 products, depending on the impact in the EIR. 02:36

6 Q. Okay. And might they also put a hold on 02:36

7 new product approvals? 02:37

8 A. Not necessarily. 02:37

9 Q. Might they? 02:37

10 A. They could. 02:37

11 Q. Could? 02:37

12 A. Uh-huh. 02:37

13 Q. Is it -- is it uncommon for a 02:37

14 manufacturer who is -- who is, to use the term 02:37

15 quote "under" a warning letter, to have new 02:37

16 product approvals stayed until the warning letter 02:37

17 is lifted? 02:37

18 MR. ANDERTON: Phil, would you read it 02:38

19 back, please? 02:38

20 THE VIDEOGRAPHER: The time is 2:40 p.m. 02:38

21 going off the record. 02:38

22 (Short break) 02:40

23 THE VIDEOGRAPHER: The time is 2:42 p.m. 02:40

24 We're back on the record. 02:40

25 MR. ANDERTON: Phil, would you please 02:40

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1 slowly read back that question? 02:40

2 (Whereupon, the testimony was read 02:40

3 back by the court reporter, as recorded above) 02:40

4 THE WITNESS: In my experience, companies 02:40

5 that are under regulatory action like a 02:40

6 warning letter or consent decree in my 02:40

7 experience is that they are allowed to 02:41

8 continue new product development and have 02:41

9 regular inspections by the FDA as it 02:41

10 progresses. 02:41

11 BY MR. ANDERTON: 02:41

12 Q. Okay. But a compliance hold is -- is 02:41

13 some restriction on the company's activities? 02:41

14 A. Yes. 02:41

15 Q. Defined by the circumstances, I 02:41

16 suppose. 02:41

17 A. Yes. 02:41

18 Q. Now, after this -- well, let's go to 02:41

19 page 11 of 40. 02:41

20 Do you see the inspection coverage heading? 02:41

21 A. Yes. 02:41

22 Q. According to that page, the quality 02:41

23 production laboratory control materials and 02:41

24 facilities and equipment systems were covered 02:41

25 during this inspection. That is five of the six 02:41

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1 systems typically inspected by the FDA; correct? 02:42

2 A. Yes. 02:42

3 Q. The only one not covered is packaging. 02:42

4 A. Packaging and labeling. 02:42

5 Q. Sorry packaging and labeling. And you 02:42

6 know packaging and labeling was in a different 02:42

7 facility from all of these other operations; 02:42

8 right? 02:42

9 A. I didn't know if it was exclusive, but I 02:42

10 know there was packaging and labeling going on in 02:42

11 another facility. 02:42

12 Q. Okay. Well, you know that it wasn't at 02:42

13 the Little Falls facility; right? 02:42

14 A. I didn't know whether there was some or 02:42

15 not. I didn't specifically look at that. 02:42

16 Q. I see. Okay. So what you didn't know 02:42

17 is whether there was packaging in another facility 02:42

18 and also at the Little Falls facility. 02:42

19 A. That's correct. 02:42

20 Q. Okay. Would you look at -- well, after 02:42

21 this inspection, another a 483 was issued. Do you 02:42

22 remember that? 02:42

23 A. Specifically, no. 02:42

24 Q. All right. Well, look at page 44 of 02:43

25 your report. 02:43

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1 A. Okay. All right. Yes. It would 02:43  
2 reflect -- you can go back and at the 483s, it 02:43  
3 would be there. 02:43

4 Q. So my question is, Dr. Bliesner, after 02:43  
5 the inspection that is reflected in the EIR, that 02:43  
6 is Plaintiffs' or, yeah, Plaintiffs' Exhibit 171, 02:43  
7 a 483 was issued; correct? 02:43

8 A. 171. Okay. I just want to make sure 02:44  
9 because we've got several different layers here. 02:44  
10 Yes. 02:44

11 Q. All right. You say so in your report. 02:44

12 A. Yes, yes. I'm just confused because we 02:44  
13 have different versions and different numbers and 02:44  
14 stuff. I wanted to be sure. 02:44

15 Q. Okay. And in that 483, there were three 02:44  
16 observations; right? 02:44

17 A. Yes, according to this. 02:44

18 Q. You lay those out on page 44 of your 02:44  
19 report and they are also set forth in this EIR; 02:44  
20 isn't that right? 02:44

21 A. Yes. 02:44

22 Q. And in among those three observations, 02:44  
23 none of them have anything do with Digitek, 02:44  
24 correct? 02:44

25 A. The general observations and supporting 02:46

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1 data, the general observations indicate there is 02:46

2 nothing referred back to Digitek. 02:46

3 Q. Okay. 02:46

4 A. Uh-huh. 02:46

5 Q. And do you know that the outcome of this 02:46

6 inspection was what is referred to as V -- as in 02:46

7 victory -- VAI? 02:46

8 A. Voluntary action indicated? 02:46

9 Q. Yes. 02:46

10 A. I don't recall. 02:46

11 Q. Do you have any reason to believe it was 02:46

12 VAI? 02:46

13 A. No. 02:47

14 Q. Okay. I mean I could put the 2008 EIR 02:47

15 in front of you that explicitly says that. 02:47

16 A. Yeah. 02:47

17 Q. Okay. 02:47

18 A. Yeah. 02:47

19 Q. So VAI is a reasonable outcome for an 02:47

20 FDA inspection; correct? 02:47

21 A. It's reasonable in that they're not 02:47

22 forcing you to do something specifically, that 02:47

23 it's up to you to do it, yes. 02:47

24 Q. Everybody would love to have NAI for all 02:47

25 -- 02:47



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1 A. Absolutely. 02:47

2 Q. -- for all inspections; right? 02:47

3 A. Absolutely. 02:47

4 Q. But VAI with three modest observations, 02:47

5 that's a favorable outcome for an inspection, 02:47

6 wouldn't you agree? 02:47

7 A. I wouldn't necessarily agree that it's a 02:47

8 modest observation. 02:47

9 Q. Well, after -- 02:47

10 A. It's better to have -- as you said, you 02:48

11 know, the real goal is no action indicated. And 02:48

12 the next step up is voluntary action indicated. 02:48

13 Q. If they weren't modest or not major at 02:48

14 least, there would have been an OAI outcome; 02:48

15 right? 02:48

16 A. Potentially. It's one of those gray 02:48

17 areas in the industry. If the agency sees you're 02:48

18 progressing and even though there are some 02:48

19 significant failures and you're implementing a 02:48

20 corrective action, then they'll go okay, VAI. 02:48

21 Q. Okay. But a VAI is a reasonable 02:48

22 outcome? 02:48

23 A. It's reasonable. 02:48

24 Q. Okay. A lot of companies never get 02:48

25 anything but VAI outcomes; right? 02:48

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1 A. I don't know lots. I mean, you know, 02:48

2 that's a broad term. 02:48

3 Q. Okay. Now continuing on this in EIR, 02:48

4 Dr. Bliesner, turn to page 25 of 40. 02:48

5 Are you there? 02:49

6 A. I'm double checking. 02:49

7 Q. Dr. Bliesner, we've already established 02:49

8 that it's the same document. 02:49

9 A. I agree. 02:49

10 Q. Okay. Then you don't need to be looking 02:49

11 at both documents. 02:49

12 A. I'm more comfortable if I do; okay. 02:49

13 What was the question please? 02:49

14 Q. I didn't ask a question. I merely 02:49

15 wanted you to turn to page 25. I asked -- the 02:49

16 question? Are you at page 25? 02:49

17 A. I am. 02:49

18 Q. Okay. Look at Exhibit 171. Okay, 02:49

19 Dr. Bliesner, you've already conceded -- 02:49

20 A. Uh-huh. 02:49

21 Q. -- that is the same EIR. There's no 02:49

22 reason to keep referring back and forth between 02:49

23 the two documents; all right? Now -- 02:49

24 MR. KERENSKY: And, Dr. Bliesner, if you 02:49

25 feel more comfortable referring back and 02:49

25 in August 2006 that resulted in a warning letter 02:50

Page 483

1 in February of 2007; right? 02:50

2 A. Yes. 02:50

3 Q. And the observation -- the EIR then goes 02:50

4 on to list all of the observations that were in 02:51

5 that prior 483. Do you see that? Starting at 02:51

6 page 25 and going all the way through, oh, all the 02:51

7 way to page 39 of the EIR; right? 02:51

8 A. So the question is, these are the 02:51

9 observations from the previous inspection that 02:51

10 happened? I'm sorry. What date? I'm confused. 02:51

11 The one in 2006? 02:51

12 Q. Correct. 02:52

13 A. Okay. 02:52

14 Q. Right. 02:52

15 A. It looks like it, yes. 483 to the EIR. 02:52

16 Q. Okay. 02:52

17 A. Yes. 02:52

18 Q. And so -- 02:52

19 A. And there were -- how many did we have 02:52

20 here? They had 13 and they went back through all 02:52

21 13, yes. 02:52

22 Q. Okay. 02:52

23 A. Uh-huh. 02:52

24 Q. So at this point during this 2007 02:52

25 inspection, as you might expect from -- as you 02:52

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1 indicated you might expect in the ordinary course, 02:52

2 the FDA reviewed the corrective actions taken by 02:52

3 Activis and assessed them or evaluated them; 02:52

4 correct? 02:52

5 A. According to the EIR, yes. 02:52

6 Q. You place great weight on FDA documents, 02:52

7 don't you, Dr. Bliesner? 02:52

8 A. I do. 02:52

9 Q. Okay. This EIR is no different than all 02:53

10 the other FDA document you give significant weight 02:53

11 to, is it? 02:53

12 A. No. 02:53

13 Q. Okay. It gets the same level of 02:53

14 credibility -- 02:53

15 A. I'm sorry. I don't know if I understand 02:53

16 your consternation there. 02:53

17 Q. Don't worry about it. 02:53

18 A. Okay, okay. 02:53

19 Q. Dr. Bliesner, did you review this 02:53

20 section of this EIR when you looked at it as you 02:53

21 compiled your report? 02:53

22 A. Yes. 02:53

23 Q. You did? 02:53

24 A. I did. 02:53

25 Q. So you must have known then in the eyes 02:53

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1 of the FDA, all of the GMP deficiencies that were 02:53  
2 part of the 2006 483 and the 2007 warning letter 02:53  
3 were remediated to the FDA's satisfaction; right? 02:53

4 A. I can't say all definitively. They have 02:54  
5 made progress and their observations were -- are 02:54  
6 here. I have to go back and look and say all is a 02:54  
7 broad term. They addressed them, yes. 02:54

8 Q. And the document speaks for itself. It 02:54  
9 will show -- 02:54

10 A. Okay. 02:54

11 Q. -- whether the FDA believed there was 02:54  
12 any unresolved corrective actions; right? 02:54

13 A. If the document -- I haven't reviewed it 02:54  
14 in a while. If it says that, then it's true. 02:54

15 Q. So as you look -- as I look at your 02:54  
16 report on pages 15 and 16 -- 02:54

17 A. Uh-huh. 02:54

18 Q. -- in chronological progression, you 02:55  
19 refer to this EIR or to the inspection that is 02:55  
20 reflected in this 2007 EIR, and you make a point 02:55  
21 to identify the three observations that the FDA 02:55  
22 issued following that inspection. Do you see that 02:55  
23 beginning at the top of page -- I'm sorry, the 02:55  
24 bottom of page 15 and continuing on to 16, 02:55  
25 paragraph 37? 02:55

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1 A. Yes. 02:55

2 Q. So you made a point of noting the 02:55

3 observations that the FDA issued after that 02:55

4 inspection; right? 02:55

5 A. That's correct. 02:55

6 Q. You didn't note the corrective actions. 02:55

7 A. That was not my intent to do a search 02:55

8 and review the documentations to look for 02:55

9 corrective actions. 02:56

10 Q. A search. You didn't have to search. 02:56

11 You read it. 02:56

12 A. Yes. 02:56

13 Q. You knew they did the corrective action 02:56

14 if you read the documents. You chose not to 02:56

15 include that positive fact in your report; right? 02:56

16 A. I suppose so, yes. 02:56

17 Q. Okay. It seems awfully selective, 02:56

18 Dr. Bliesner, don't you think so? 02:56

19 A. No, not at all. 02:56

20 Q. Okay. 02:56

21 A. I was looking for patterns of lack of 02:56

22 compliance which continued all the way up to the 02:56

23 second consent decree. 02:56

24 Q. Except that in the eyes of the FDA, all 02:56

25 prior GMP deficiencies had been corrected as of 02:56

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1 the time this inspection occurred, except for 02:56  
2 those three new observations. 02:56

3 A. Of the original observations, yes. 02:56

4 Q. So as of the time that inspection was 02:56  
5 completed, in the eyes of the FDA, the GMP 02:56  
6 deficiencies that existed at Activis Totowa were 02:56  
7 those three observations? 02:56

8 A. At that point, yes. 02:56

9 Q. Okay. So when you say in a broad, 02:56  
10 sweeping fashion that they continued right up 02:57  
11 through the second consent decree, that's not 02:57  
12 accurate, is it? 02:57

13 A. I disagree. You can correct actions and 02:57  
14 put them in place but still not change the 02:57  
15 fundamental systems. You can correct the 02:57  
16 procedures but you didn't necessarily change the 02:57  
17 system, and that was shown when they got a second 02:57  
18 consent decree after this. 02:57

19 Q. The FDA audited all of those systems; 02:57  
20 right? 02:57

21 A. If this was done under the compliance 02:57  
22 program guidance manual where they look at quality 02:57  
23 systems base, there was a turn in here. Let me 02:57  
24 just check because the agency hasn't always looked 02:57  
25 at it from a quality systems standpoint. 02:57



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1 Q. Well, Dr. Bliesner, you already 02:58

2 acknowledged that the FDA conducted an inspection 02:58

3 of five of the six major systems. The only one 02:58

4 not there is packaging and labeling; right? 02:58

5 A. That's correct. 02:58

6 Q. So the FDA issued its written opinion 02:58

7 that the company had corrected all outstanding 02:58

8 previously identified GMP deficiencies except for 02:59

9 the three new ones that they identified as of the 02:59

10 time they conducted this inspection; is that 02:59

11 right? 02:59

12 A. They corrected the actions that they had 02:59

13 made the observations on. 02:59

14 Q. Okay. So -- 02:59

15 A. That doesn't mean it was a systems-based 02:59

16 correction. It was a correction of those specific 02:59

17 actions. 02:59

18 Q. Do you want go through each one, 02:59

19 Dr. Bliesner? You're so insistent on qualifying 02:59

20 your responses -- again to keep doors open as 02:59

21 you've been coached to do -- that you can't 02:59

22 concede the FDA -- the viability of this FDA 02:59

23 document. You can't have it both ways. 02:59

24 Do you understand that? 02:59

25 MR. KERENSKY: Objection, form. 02:59

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1 BY MR. ANDERTON: 02:59

2 Q. If you want to give credit to FDA 02:59

3 documents -- 02:59

4 A. Yes. 02:59

5 Q. -- as a substantial basis for your 02:59

6 opinion -- 02:59

7 A. Yes. 02:59

8 Q. -- you must credit the documents that 02:59

9 don't necessarily align with your opinion. You 02:59

10 understand that; right? 02:59

11 MR. KERENSKY: Objection form. Not a 02:59

12 true statement. 03:00

13 THE WITNESS: I would disagree with that. 03:00

14 BY MR. ANDERTON: 03:00

15 Q. You can pick and choose? 03:00

16 A. I'm not picking and choosing. It's just 03:00

17 that there's been a progression with the FDA's 03:00

18 inspection procedures over the years. 03:00

19 Q. Right. 03:00

20 A. Where they would go in and look at these 03:00

21 major components; right? But they wouldn't 03:00

22 necessarily look at their internal document that 03:00

23 says how you do an inspection by a quality 03:00

24 systems-based approach. That didn't happen until 03:00

25 later on. 03:00

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1 Looking at this cover document right now, I'm 03:00  
2 not sure whether they implemented the new quality 03:00  
3 systems-based approach further. 03:00

4 Q. Do you have any reason to believe they 03:00  
5 didn't? 03:00

6 A. Potentially, yes. 03:00

7 Q. What's that? 03:00

8 A. Because if I'm not mistaken -- and we 03:00  
9 can look it up -- the next inspection which 03:00  
10 resulted in the consent decree, they specifically 03:00  
11 say this inspection was conducted using the FDA 03:00  
12 compliance program guidance manual and the number. 03:00

13 Q. Okay. So -- 03:00

14 A. And I don't see that they did that 03:00  
15 here. That's why I'm bringing up the point. I'm 03:00  
16 not trying to be difficult. I just -- again, the 03:00  
17 agency's made significant progress over the course 03:00  
18 since like 2002 when they adopted the quality 03:01  
19 systems-based approach and they didn't necessarily 03:01  
20 implement it in full force all the way out. 03:01  
21 That's all it is. 03:01

22 Q. So you're going to, as I said, that's a 03:01  
23 long-winded way of saying you're going to 03:01  
24 discredit this FDA document and give some limited 03:01  
25 weight to others. 03:01

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1 A. I'm not discrediting it all; okay? As a 03:01  
2 matter of fact, all right, we're back on Exhibit 03:01  
3 171. I missed when we went first through. 03:01

4 Q. And look at that -- 03:01

5 A. Inspection. 03:01

6 Q. Inspectional guidance was afforded -- 03:01

7 A. Through compliance program and guidance 03:01  
8 manuals. 73506002. So with that being said, yes, 03:01  
9 they would use the newest guidance documents to 03:01  
10 look at it from a quality systems-based approach. 03:01

11 Q. So does that change your earlier 03:01  
12 testimony or allow you to accept the fact that as 03:01  
13 of the date, this inspection was concluded in the 03:01  
14 eyes of the FDA? 03:01

15 A. Uh-huh. 03:01

16 Q. Activis had corrected all prior GMP 03:01  
17 deficiencies and the only GMP deficiencies the FDA 03:02  
18 identified were the three new ones that are set 03:02  
19 forth in that -- after this inspection. 03:02

20 A. They corrected all of the findings that 03:02  
21 came up with the 483. I wouldn't -- I'm not 03:02  
22 disputing that at all. 03:02

23 Q. Okay. 03:02

24 A. All right. 03:02

25 Q. And after -- 03:02

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1 A. And they were recidivistic though 03:02

2 because obviously they went back to their old 03:02

3 ways. That's why they got a consent decree. 03:02

4 That's the real problem with companies ending up 03:02

5 in consent decree. They will get through warning 03:02

6 letters, you know -- 03:02

7 Q. Dr. Bliesner, there's no question 03:02

8 pending. 03:02

9 A. Oh, I'm sorry. 03:02

10 MR. KERENSKY: No, I'm sorry. He can say 03:02

11 whatever in his question and you can't stop 03:02

12 him. 03:02

13 MR. ANDERTON: No, he can't, Mike. There 03:02

14 was no -- 03:02

15 MR. KERENSKY: Non-responsive, that's 03:02

16 your remedy. 03:02

17 MR. ANDERTON: There was no question 03:02

18 pending. 03:02

19 MR. KERENSKY: He was still answering the 03:02

20 last question. 03:02

21 MR. ANDERTON: No, he wasn't. 03:02

22 MR. KERENSKY: Do not interrupt the 03:02

23 witness. 03:02

24 MR. ANDERTON: He just started talking 03:02

25 gratuitously. 03:02

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1	MR. KERENSKY: That is not true.	03:02
2	MR. ANDERTON: It is true. There's no	03:02
3	question pending.	03:03
4	MR. KERENSKY: Are you refusing to let	03:03
5	the witness continue his answer?	03:03
6	MR. ANDERTON: There is no answer, Mike.	03:03
7	MR. KERENSKY: Are you refusing to let	03:03
8	the witness finish his answer?	03:03
9	MR. ANDERTON: He finished his answer and	03:03
10	then just started talking again without a	03:03
11	question being posed to him.	03:03
12	MR. KERENSKY: Are you refusing to let	03:03
13	the witness finish his answer?	03:03
14	MR. ANDERTON: Mike, you can't instruct	03:03
15	him to talk. There's no question pending.	03:03
16	MR. KERENSKY: I'm not -- there is a	03:03
17	question pending.	03:03
18	MR. ANDERTON: No, there is not.	03:03
19	MR. KERENSKY: You interrupted him. Are	03:03
20	you refusing to let him finish his answer?	03:03
21	THE WITNESS: He's finished his answer.	03:03
22	I'm not refusing anything.	03:03
23	MR. KERENSKY: I'm sorry. The record is	03:03
24	real clear. You interrupted him and told him	03:03
25	to stop because you thought he was answering	03:03

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1 something other than what you asked him. 03:03

2 MR. ANDERTON: No, because -- 03:03

3 MR. KERENSKY: Your objection is 03:03

4 unresponsive, not to stop him from talking and 03:03

5 tell him he's just -- he's not answering. 03:03

6 MR. ANDERTON: Mike, if you want to clean 03:03

7 this up with questions, you certainly may. 03:03

8 We're going to move on. 03:03

9 MR. KERENSKY: I'm sorry. We're going to 03:03

10 stop the deposition until he finishes his 03:03

11 answer. 03:03

12 MR. ANDERTON: No we're not -- there is 03:03

13 no question pending, Mike. 03:03

14 MR. KERENSKY: There is. 03:03

15 MR. ANDERTON: No, there isn't. He 03:03

16 answered my question. 03:03

17 MR. KERENSKY: Tell you what. Let's have 03:04

18 the court reporter go back and read it. 03:04

19 MR. ANDERTON: Mike, if you -- 03:04

20 MR. KERENSKY: Read the question and the 03:04

21 answer, please. And the answer and 03:04

22 Mr. Anderton's interruption. 03:04

23 MR. ANDERTON: If you keep obstructing 03:04

24 this deposition and instructing the witness 03:04

25 what to say, we're going to call the court. 03:04

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1 MR. KERENSKY: I think it's a good time 03:04  
2 to call the court. 03:04

3 MR. ANDERTON: I mean he was done and had 03:04  
4 moved on, and I was about to ask another 03:04  
5 question, and he just started talking. 03:04

6 MR. KERENSKY: I accept your invitation 03:04  
7 to call the court so he can hear the last 03:04  
8 question, the last answer, your interruption. 03:04

9 MR. ANDERTON: There is no interruption. 03:04  
10 I interrupted something that he was saying in 03:04  
11 response to no question. 03:04

12 MR. KERENSKY: That is not my take on it, 03:04  
13 but your remedy if you think that, is to say 03:04  
14 unresponsive. 03:04

15 MR. ANDERTON: Your remedy is to clear it 03:04  
16 up if you think there's something here was 03:04  
17 answering in response to one of my questions. 03:04  
18 You have that right. Now we're moving on. 03:04

19 MR. KERENSKY: I do not think that. And 03:04  
20 no, he's not going to ask answer any more 03:04  
21 questions until you let him finish his 03:05  
22 answer. 03:05

23 MR. ANDERTON: What's the basis for you 03:05  
24 instructing him not to answer? 03:05

25 MR. KERENSKY: Because you interrupted 03:05



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1 him. 03:05

2 MR. ANDERTON: There was no question 03:05

3 pending. 03:05

4 MR. KERENSKY: I'm sorry. There was. 03:05

5 MR. ANDERTON: There wasn't, Mike. Now, 03:05

6 I'm not going to argue with you anymore. This 03:05

7 is ridiculous. 03:05

8 MR. KERENSKY: Okay. Well, Dr. Bliesner, 03:05

9 start packing up. 03:05

10 MR. ANDERTON: You cannot instruct him to 03:05

11 stop the deposition, Mike. 03:05

12 MR. KERENSKY: Sure I can. 03:05

13 MR. ANDERTON: No, you can't. 03:05

14 MR. KERENSKY: I just did. Until he 03:05

15 finishes that answer, we're not going to do 03:05

16 any more, or we can call the judge. 03:05

17 MR. ANDERTON: Read the question back, 03:05

18 Phil. 03:05

19 MR. KERENSKY: There you go. And the 03:05

20 answer and the interruption, please, Phil. 03:05

21 (Whereupon, the testimony was read 03:07

22 back by the court reporter, as recorded above) 03:07

23 MR. ANDERTON: So what that shows, Mike, 03:07

24 is that in fact -- 03:07

25 MR. KERENSKY: I am not done listening, 03:07

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1	Michael.	03:07
2	MR. ANDERTON: Listen carefully, Mike,	03:07
3	because what you'll see that in fact	03:07
4	Dr. Bliesner interrupted my question.	03:07
5	MR. KERENSKY: That's an interesting	03:07
6	interpretation.	03:07
7	MR. ANDERTON: Read it back, Phil.	03:07
8	(Whereupon, the testimony was read	03:07
9	back by the court reporter, as recorded above)	03:07
10	MR. KERENSKY: Your question obviously	03:07
11	interrupted his answer inadvertently that time	03:07
12	and then the second time intentionally.	03:07
13	MR. ANDERTON: Mike, not true. Read it	03:07
14	back.	03:07
15	MR. KERENSKY: That's my take on it.	03:07
16	MR. ANDERTON: Read it back, Phil.	03:07
17	MR. KERENSKY: I'm telling you I'm not	03:07
18	going to let you do this. I'm not going to	03:07
19	let you do it. Call the judge now. It's real	03:07
20	simple. We can call the judge now, we can	03:07
21	stop the deposition, or you can stop, let him	03:07
22	say what he wants to say, and to finish this	03:07
23	question to talk about recidivism.	03:07
24	MR. ANDERTON: There was no question	03:07
25	about that.	03:07

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1 MR. KERENSKY: And then you can object. 03:07

2 MR. ANDERTON: And I object to you to 03:07

3 your speaking -- 03:07

4 MR. KERENSKY: There are three choices 03:07

5 you've got right now. Pick one. 03:07

6 MR. ANDERTON: I'm sorry. Are you -- 03:07

7 THE WITNESS: Can I take a break? 03:08

8 MR. KERENSKY: Yeah, go ahead Dave. 03:08

9 MR. ANDERTON: Wait a minute. I'm sorry, 03:08

10 Mike. Do you get to decide now? 03:08

11 MR. KERENSKY: Yeah. 03:08

12 MR. ANDERTON: This witness is stopping 03:08

13 this deposition every 30 minutes. Why are we 03:08

14 doing that? 03:08

15 MR. KERENSKY: Because I don't know. 03:08

16 It's a very grueling deposition. You're one 03:08

17 of the toughest guys I've been around in a 03:08

18 long time. It's very difficult. 03:08

19 MR. ANDERTON: Mike, stop. Why are we 03:08

20 stopping every 30 minutes? 03:08

21 THE WITNESS: Because I got to go to the 03:08

22 bathroom. 03:08

23 MR. ANDERTON: Then go to the restroom. 03:08

24 THE VIDEOGRAPHER: The time is 3:10 p.m. 03:08

25 We are going off the record. 03:08

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1 (Short break) 03:17

2 THE VIDEOGRAPHER: The time is 3:19 p.m. 03:17

3 We are back on the record. This is the 03:17

4 beginning of tape seven. 03:17

5 MR. KERENSKY: I would like the court 03:17

6 reporter to finish reading the witness's last 03:17

7 answer and I ask he be allowed to finish that 03:17

8 answer. 03:17

9 MR. ANDERTON: Go head, Phil. 03:18

10 (Whereupon, the testimony was read 03:18

11 back by the court reporter, as recorded above) 03:18

12 MR. KERENSKY: That's a good place to 03:18

13 stop. Dr. Bliesner, do you need to add to 03:18

14 that answer? 03:18

15 THE WITNESS: Read the last part of that 03:18

16 again, please. Just the -- not the whole 03:18

17 thing, just the last sentence. 03:18

18 (Whereupon, the testimony was read 03:18

19 back by the court reporter, as recorded above) 03:18

20 And try to implement corrective actions. 03:18

21 And when they do so, they're not 03:18

22 systems-based, quality systems-based and they 03:18

23 go right back to it because it's a culture 03:19

24 that comes along with it. And it's not a true 03:19

25 corrective action that stands up to scrutiny. 03:19

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1 MR. ANDERTON: Move to strike that entire 03:19  
2 speech as utterly non-responsive. Responsive 03:19  
3 to no pending question. 03:19  
4 BY MR. ANDERTON: 03:19  
5 Q. The -- you testified last time 03:19  
6 Dr. Bliesner that -- and I want to read it because 03:19  
7 I think it is interesting and because I'd like to 03:19  
8 be accurate. 03:20  
9 Mr. Moriarty asked you a question at page 117 03:20  
10 and carrying over on to page 118. You gave a 03:20  
11 response and during that response you said, and I 03:20  
12 quote: "This is the first time I went up to my 03:20  
13 medicine cabinet and I looked for anything that 03:20  
14 had an Activis label on it and flushed it down the 03:20  
15 toilet because it was that gross in terms of what 03:20  
16 I was seeing." 03:20  
17 Do you remember that testimony? 03:20  
18 A. I do. 03:20  
19 Q. What did you flush down the toilet? 03:20  
20 A. Products that had Activis's name on it. 03:21  
21 Q. Such as? 03:21  
22 A. I don't recall specifically. 03:21  
23 Q. Did you have products that had Activis's 03:21  
24 name on it? 03:21  
25 A. I did. 03:21

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1 Q. How many? 03:21

2 A. I don't recall. I think one bottle. 03:21

3 Q. One bottle. Was it for you or for 03:21

4 another family member? 03:21

5 A. It was for me. 03:21

6 Q. So you don't even know what you flushed 03:21

7 down the toilet. 03:21

8 A. I don't recall. It was a such a gross 03:21

9 failure of compliance I didn't want to be putting 03:21

10 it in my body. 03:21

11 Q. Well, you had to go out and replace it; 03:21

12 right? It was a prescription medication? 03:21

13 A. Yes. 03:21

14 Q. So what did you go replace? 03:21

15 A. You'll find somebody else that 03:21

16 manufactures. You ask the pharmacist to give you 03:21

17 a different replacement. 03:21

18 Q. What was it? What did you replace? 03:21

19 A. I don't recall what I replaced 03:21

20 Q. Well, it was sometime in the last 12 03:21

21 months. You don't remember? 03:21

22 A. No. 03:21

23 Q. That seems like a pretty striking 03:21

24 event. You ran up to your medicine cabinet. 03:21

25 A. Yes, sir. 03:21

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1 Q. You threw open the door and you flushed 03:21  
2 medicine down the toilet. 03:21  
3 A. I did. 03:21  
4 Q. Was that medicine manufactured by 03:21  
5 Activis Elizabeth or Activis Totowa? 03:21  
6 A. I wouldn't know. It didn't say on the 03:22  
7 bottle. 03:22  
8 Q. You didn't even check, did you? 03:22  
9 A. I don't believe that the bottle tells 03:22  
10 you where it's manufactured. 03:22  
11 Q. You didn't check, did you? 03:22  
12 A. I didn't have to. 03:22  
13 Q. Sure you did. What do you mean you 03:22  
14 didn't have to? 03:22  
15 A. Because of the failure in the quality 03:22  
16 systems that I had seen in reviewing the document, 03:22  
17 I didn't want to take any of the company's 03:22  
18 product. 03:22  
19 Q. Well, do you know anything about the 03:22  
20 distinction between Activis Totowa and Activis 03:22  
21 Elizabeth? 03:22  
22 A. From a business standpoint, not 03:22  
23 specifically. 03:22  
24 Q. Do you know who manufactured what 03:22  
25 products? 03:22

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1 A. If I go back and review, I can piece 03:22

2 together a list. 03:22

3 Q. Well, you shouldn't -- 03:22

4 A. I can't right off the top of my head. 03:22

5 Q. You shouldn't have any information about 03:22

6 Activis Elizabeth. They're not party to this 03:22

7 lawsuit. Do you know that Activis Elizabeth and 03:22

8 Activis Totowa work out of two totally different 03:22

9 facilities? 03:22

10 A. I know they are two different locations, 03:22

11 yes. 03:22

12 Q. And you know they have two totally 03:22

13 different quality systems? 03:22

14 A. No, I don't. 03:22

15 Q. Different leadership? 03:22

16 A. No, I don't. 03:22

17 Q. Different personnel? 03:22

18 A. No, I don't. 03:22

19 Q. Didn't bother to try to find out, did 03:22

20 you? 03:22

21 A. I was told not to review them. 03:22

22 Q. I'm talking about when you were in such 03:23

23 a hurry to flush your medicine down the toilet, 03:23

24 you didn't bother to try to find out whether that 03:23

25 product came from Activis Totowa or from Activis 03:23



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1 Elizabeth or from another Activis entity. 03:23

2 A. No, I didn't. 03:23

3 Q. Is that a logical, reasoned reaction to 03:23  
4 anything? 03:23

5 A. Yes. 03:23

6 Q. You said last time that -- you made 03:23  
7 reference to your belief or you indicated -- I 03:23  
8 shouldn't say may reference to -- you indicated 03:23  
9 your belief that the FDA puts things on its 03:23  
10 website that are pure politics. 03:23

11 Do you remember that testimony? 03:23

12 A. I did not make that blanket statement 03:23  
13 that I recall. 03:24

14 Q. Well, let me ask you this. 03:24

15 A. Okay. 03:24

16 Q. When you conducted an analysis that you 03:24  
17 did to issue your opinion in this case -- 03:24

18 A. Yes. 03:24

19 Q. -- did you do a political analysis or 03:24  
20 some other type of analysis? 03:24

21 A. I reviewed the documentation as I would 03:24  
22 if I was a client in the facility looking for data 03:24  
23 to support whatever conclusions come up. 03:24

24 Q. Is that a political analysis? 03:24

25 A. No. 03:24

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1 Q. Did politics enter into your analysis at 03:24  
2 all? 03:24  
3 A. No. 03:24  
4 Q. Are you an expert in politics? 03:24  
5 A. No. 03:24  
6 Q. Do you have anything to support your 03:24  
7 testimony that things the FDA puts on its website 03:24  
8 result from politics? 03:24  
9 A. In my experience, there are sometimes 03:25  
10 competing opinions against different branches 03:25  
11 within FDA which appear to be -- appear to be 03:25  
12 politically motivated. 03:25  
13 Q. Appear to be politically motivated? 03:25  
14 A. Yes. 03:25  
15 Q. Bliesner on politics? Is that the 03:25  
16 source for that, Bliesner on politics? 03:25  
17 A. No, it's not Bliesner on politics. 03:25  
18 Q. What observation -- what supports that 03:25  
19 observation? 03:25  
20 A. My experience. 03:25  
21 Q. Do you have any political experience? 03:25  
22 A. Political? 03:25  
23 Q. Yes. 03:25  
24 A. Like in formal office or running for 03:25  
25 anything like that? 03:25

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1 Q. Yes. 03:25

2 A. No. 03:25

3 Q. Did you ever work for the FDA? 03:25

4 A. No. 03:25

5 Q. Did you ever spend any time inside 03:25

6 either one of the various branches? Well not 03:25

7 either one. Any of the various branches of the 03:26

8 FDA? 03:26

9 A. No. 03:26

10 Q. So you believe that when one branch 03:26

11 issues something that isn't necessarily consistent 03:26

12 with something issued by another branch, it's 03:26

13 strictly politics? 03:26

14 A. Not strictly. There are components to 03:26

15 it that do arise. For instance, drug shortage 03:26

16 often has serious discussions with compliance 03:26

17 group because they have different missions 03:26

18 Q. Have you ever been party to any of those 03:26

19 discussions? 03:26

20 A. Directly, no. 03:26

21 Q. So you have no idea what is said in 03:26

22 those discussions between -- I'm sorry drug 03:26

23 shortage and compliance; right? 03:26

24 A. Meaning the folks that are in charge of 03:26

25 making sure they're supplied to market and the 03:26

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1 compliance people. 03:26

2 Q. You have no idea what's ever been said 03:26

3 in any of those conversations; right? 03:26

4 A. That's not true. 03:26

5 Q. Have you ever been -- 03:26

6 A. I've not sat in meetings. I have 03:26

7 clients convey it. 03:26

8 Q. Clients who sat in the meetings? 03:26

9 A. Yes. 03:27

10 Q. So you're getting it at least third 03:27

11 hand? 03:27

12 A. Second-hand. 03:27

13 Q. Second-hand? 03:27

14 A. Yes. 03:27

15 Q. Ever do anything to verify that? 03:27

16 A. Specifically, no. 03:27

17 Q. I want to talk about -- 03:27

18 A. Can you adjust the air-conditioning in 03:27

19 here? I'm starting to get to the same point. 03:27

20 MS. DREWES: I will. But I tried earlier 03:27

21 and she turned it down as much as she could. 03:27

22 Apparently it's an issue especially later in 03:27

23 the day when the sun comes around. 03:27

24 MR. ANDERTON: Comes around this side of 03:27

25 the building. 03:27

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1 MR. KERENSKY: It's getting hot in here, 03:28

2 too. It must be coming right over the phone. 03:28

3 MR. ANDERTON: Yeah. 03:28

4 BY MR. ANDERTON: 03:28

5 Q. You produced today invoices that you 03:28

6 have submitted to the Plaintiffs' counsel for 03:28

7 payment; right? 03:28

8 A. Yes. 03:28

9 Q. You said there's least one that's 03:28

10 outstanding; right? 03:28

11 A. Yes. 03:28

12 Q. I don't -- there is no detail on those 03:28

13 invoices. Do you have detailed time records that 03:28

14 show what you did and how many hours you spent 03:28

15 besides a general summary as is set forth in these 03:28

16 invoices? 03:28

17 A. I just have a spreadsheet where I did 03:28

18 the work, I put the hour in and then I send that 03:28

19 to the bookkeeper. 03:28

20 Q. Okay. So you do have records? 03:28

21 A. Uh-huh. 03:28

22 Q. Do you provide any description of what 03:28

23 you did during the -- 03:28

24 A. On those records? 03:28

25 Q. Yes. 03:28

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1 A. I don't believe so. There may be a word 03:28  
2 or two. 03:28  
3 Q. Services rendered. Is that the -- 03:28  
4 A. I'd have to look at -- I'm fairly 03:28  
5 certain that I provided those sheets. 03:29  
6 Q. On? 03:29  
7 A. The hard drive, I think. 03:29  
8 Q. Oh, in the hard drive? 03:29  
9 A. I think so. 03:29  
10 Q. Okay. 03:29  
11 A. If not, I can get them for you. 03:29  
12 Q. Do you know how much money you have 03:29  
13 billed and been paid from this engagement? 03:29  
14 A. To this point? 03:29  
15 Q. Yes. 03:29  
16 A. No. 03:29  
17 Q. Is there only one invoice that's 03:29  
18 outstanding beyond this one? 03:29  
19 A. I'm fairly certain yes, there is. 03:29  
20 Q. Rough estimate puts it somewhere north 03:29  
21 of \$140,000. Does that sound right? 03:29  
22 A. If you add it up and that's what the 03:30  
23 number is, then it is. I really don't know. 03:30  
24 Q. How many other engagements did you have 03:30  
25 in 2010? 03:30

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1 A. Engagements, you mean consulting 03:30  
2 projects? 03:30  
3 Q. Uh-huh. 03:30  
4 A. One for sure. It's still ongoing. And 03:30  
5 I may have had one other just briefly. 03:30  
6 Q. Any of them as big as this one? 03:30  
7 A. And when you say "big," what do you mean 03:30  
8 by big? 03:30  
9 Q. Well \$140,000, that's a reasonable 03:30  
10 amount of revenue wouldn't you say? 03:30  
11 A. It is. 03:30  
12 Q. I mean even at 550 an hour, that's 700 03:30  
13 hours; right? No, that's wrong. 03:30  
14 A. I can tell you this. I've been fully 03:31  
15 engaged with a client since June. 03:31  
16 Q. In addition to this engagement? 03:31  
17 A. Yes. This is on the side. 03:31  
18 Q. Oh, this is on the side? 03:31  
19 A. Prior to -- it started prior to and then 03:31  
20 this -- this has been done on weekends. 03:31  
21 Q. Okay. 03:31  
22 A. I do anything about 60 to 90 hours a 03:31  
23 week at that current client site. I have been 03:31  
24 since June. 03:31  
25 Q. Okay. Will you pick up Exhibit 109? 03:31

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1 A. Sure, if I can find it. Which one is 03:31

2 that, sir? 03:31

3 Q. It's one of the sets of notes that you 03:31

4 produced that we took last time. 03:32

5 A. Yes, got it. 03:32

6 Q. I'm looking at the first page of 109. 03:32

7 Are you with me? 03:32

8 A. I am. 03:32

9 Q. Roman numeral I -- on 109, the first 03:32

10 page is as I read the heading, "Collective Proof 03:32

11 of Adulterated Digitek Making it to Market." 03:32

12 A. Yes. 03:32

13 Q. The first item Roman numeral I is 03:32

14 Adverse Event Reports; right? 03:32

15 A. Yes. 03:32

16 Q. You are not a pharmacovigilance expert, 03:32

17 are you? 03:32

18 A. I am not. 03:32

19 Q. You don't know -- you're not able to 03:32

20 give any expert opinion about the reliability of 03:32

21 the facts and circumstances in adverse event 03:32

22 reports, are you? 03:33

23 A. No, this was based on observation that 03:33

24 was in one of the EIRs. I'd have to look. 03:33

25 Q. Okay. What you mean by that? 03:33



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1 A. There was a -- in reviewing, if I'm not 03:33  
2 mistaken an EIR or 483, that this is one of the 03:33  
3 items the agency found specifically. 03:33

4 There was a death within a certain period of 03:33  
5 time or whatever, so... 03:33

6 Q. That was the report? 03:33

7 A. Yes. 03:33

8 Q. That wasn't a finding of the EIR. 03:33

9 A. It was a report. 03:33

10 Q. Yeah. 03:33

11 A. That there was a death from an adverse 03:33  
12 event and it was not reported to the FDA. 03:33

13 Q. So agency, to be clear -- 03:33

14 A. Uh-huh. 03:33

15 Q. -- the agency, the FDA didn't find that 03:33  
16 there was a death within several hours of taking 03:33  
17 the product. 03:33

18 A. They found there was an adverse event 03:33  
19 that had not been reported to them that stated 03:33  
20 that there was a death within a certain short 03:33  
21 period of time, yeah. 03:33

22 Q. And, again, you're not qualified to 03:33  
23 assess the reliability of the facts and 03:33  
24 circumstances that are set forth in or were set 03:34  
25 forth in that adverse event, are you? 03:34

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1 A. No, but it triggered my eye because it 03:34  
2 was a short period of time for an immediate dose 03:34  
3 of product, and it was like maybe there's 03:34  
4 something. That was actually the first thing that 03:34  
5 got me started on this -- this review. 03:34

6 Q. Well, Dr. Bliesner, I'm a little bit 03:34  
7 confused. 03:34

8 A. Uh-huh. 03:34

9 Q. You say -- when you make that statement 03:34  
10 -- 03:34

11 A. Uh-huh. 03:34

12 Q. -- you're presuming the accuracy or -- 03:34  
13 I'm sorry. You're presuming the cause and effect 03:34  
14 relationship between taking a product and the 03:34  
15 event set forth in the adverse event report, 03:34  
16 aren't you? 03:34

17 A. Say that again specifically. 03:34

18 MR. ANDERTON: Phil, would you please 03:35  
19 read that back? 03:35

20 (Whereupon, the testimony was read 03:35  
21 back by the court reporter, as recorded above) 03:35

22 THE WITNESS: There is a potential cause 03:35  
23 and effect there. 03:35

24 BY MR. ANDERTON: 03:35

25 Q. Potential? 03:35

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1 A. Yes. 03:35

2 Q. Which you've said you're not qualified 03:35

3 to evaluate. 03:35

4 A. No, that's correct. 03:35

5 Q. Okay. 03:35

6 A. But the potential was there, which 03:35

7 from -- would you like me to continue or stop? I 03:35

8 don't want to... 03:35

9 Q. You were answering. 03:35

10 A. Okay. From a, you know, compliance 03:35

11 standpoint, you look at that and you say to 03:35

12 yourself, jeez, if there was an adverse event, a 03:35

13 person potentially passed away in two and a half 03:35

14 hours, you sit back and go okay, from a product 03:35

15 standpoint, me working for this company again, 03:35

16 from a product standpoint, jeez, could that have 03:35

17 been product-related? 03:35

18 So you go look and you see it's immediate 03:35

19 dosage form, and you try to pull up the PK lead 03:35

20 out of an ANDA. And if the PK says it's like six 03:35

21 hours or whatever, you don't worry about it. You 03:35

22 move on. It's not related to that. That's how 03:35

23 the logic went on that. 03:35

24 Q. Okay. And so is that proof that 03:35

25 adulterated Digitek made it to market? 03:35

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1 A. No, it's not proof. 03:35

2 Q. Okay. You characterize it as such in 03:35

3 this document. That's just why I'm -- 03:36

4 A. My notes -- 03:36

5 Q. Okay. 03:36

6 A. Proof is -- 03:36

7 Q. So it's not proof? 03:36

8 A. No, it's not. It's a piece of data that 03:36

9 was the start of a potential pattern that was the 03:36

10 first thing -- quite honestly that was first thing 03:36

11 that caught my eye so I just started digging. 03:36

12 Q. I'm merely asking about your 03:36

13 characterization in your document. 03:36

14 A. Yes. 03:36

15 Q. So it's not proof. 03:36

16 A. No. 03:36

17 Q. And look at Roman numeral VI. 03:36

18 A. Okay. 03:36

19 Q. Company internal documents and 03:36

20 investigations. 03:36

21 A. Uh-huh. 03:36

22 Q. You see your reference to purchase 03:36

23 presses. 03:36

24 A. Yes. 03:36

25 Q. How is that proof that adulterated 03:36

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1 Digitek made it to market? 03:36

2 A. There were a couple of circumstances as 03:36

3 I recall where they had reasonable suspect that 03:36

4 they had problems with tablet presses. So they 03:37

5 committed -- if I'm not mistaken without taking 03:37

6 more time and going back and looking at the 03:37

7 document -- they would purchase new presses with 03:37

8 weight controls or whatever and they never did. 03:37

9 And that happened over the course of a -- if I'm 03:37

10 not mistaken, going back to look at the book, a 03:37

11 year or two. 03:37

12 Q. Okay. So you work with companies all 03:37

13 the time on GMP compliance; right? 03:37

14 A. That's correct. 03:37

15 Q. And one of the things I'm sure you tell 03:37

16 them is that they ought to be constantly 03:37

17 evaluating and reevaluating their quality systems; 03:37

18 right? 03:37

19 A. Absolutely. CGMP current today, not 03:37

20 yesterday. 03:37

21 Q. Exactly. And so it's an evolutionary 03:37

22 process. 03:37

23 A. Absolutely. 03:37

24 Q. Never stops evolving. 03:37

25 A. No, it doesn't. 03:37

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1 Q. So upgrading presses or purchasing new 03:37  
2 presses -- 03:37  
3 A. Uh-huh. 03:37  
4 Q. -- doesn't say anything about whether 03:37  
5 adulterated product was produced or made it to 03:38  
6 market, does it? 03:38  
7 A. It doesn't say anything about whether 03:38  
8 adulterated products have made it to the market. 03:38  
9 Q. That's right. 03:38  
10 A. I wouldn't agree with that statement. 03:38  
11 It -- it shows they had problems. 03:38  
12 Q. It does? 03:38  
13 A. It shows they had problems with the 03:38  
14 presses because they said they had problems with 03:38  
15 the presses. 03:38  
16 Q. They didn't say they had problems. They 03:38  
17 said they wanted to purchase new presses 03:38  
18 A. With weight control, if I remember 03:38  
19 correctly. 03:38  
20 Q. Okay. So that doesn't mean they're 03:38  
21 having problems; it means they're looking at a 03:38  
22 different technology. 03:38  
23 A. Uh-huh. 03:38  
24 Q. Right? 03:38  
25 A. Yes, an upgrade if you will. 03:38

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1 Q. Well, let's call it an upgrade. 03:38

2 A. Uh-huh. 03:38

3 Q. Doesn't mean you had problems before; 03:38

4 right? 03:38

5 A. But they committed to the FDA and they 03:38

6 didn't purchase them, as I recall. 03:38

7 Q. You just changed the subject, 03:38

8 Dr. Bliesner. 03:38

9 A. I did? 03:38

10 Q. Yeah? 03:38

11 A. I'm sorry. 03:38

12 Q. I asked you if the mere act of upgrading 03:38

13 presses means that they had problems. 03:38

14 A. Not specifically, no. 03:39

15 Q. And so purchasing presses doesn't 03:39

16 constitute proof that there is adulterated Digitek 03:39

17 in the market, does it? 03:39

18 A. Not necessarily, no. 03:39

19 Q. But you characterize it on that 03:39

20 document. 03:39

21 A. It's my notes, uh-huh. 03:39

22 Q. You understand, Dr. Bliesner? 03:39

23 A. I do sir. 03:39

24 Q. That we get these documents. 03:39

25 A. Uh-huh. 03:39

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1	Q.	And we get your report?	03:39
2	A.	Uh-huh.	03:39
3	Q.	And we are -- we have to try to figure	03:39
4	out --		03:39
5	A.	Uh-huh.	03:39
6	Q.	-- how you reached the conclusions that	03:39
7	you reached.		03:39
8	A.	Correct.	03:39
9	Q.	That's what we're doing today.	03:39
10	A.	I understand.	03:39
11	Q.	So I understand that this is your notes.	03:39
12	A.	Uh-huh.	03:39
13	Q.	You're the one who characterized this as	03:39
14	proof --		03:39
15	A.	Uh-huh.	03:39
16	Q.	-- that adulterated Digitek was in the	03:39
17	market.		03:39
18	A.	Uh-huh.	03:39
19	Q.	I'm just inquiring about some of these	03:39
20	things.		03:39
21	A.	Understood.	03:39
22	Q.	Excuse me?	03:40
23	A.	Uh-huh.	03:40
24	Q.	Dr. Bliesner, would you now find Exhibit	03:40
25	107.	It's another set of notes that we collected	03:40



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1 from you last time. 03:40

2 A. May I see the top of? 03:40

3 Q. You may. It the thicker one. It's the 03:40

4 Mylan deposition exhibits. 03:40

5 A. I have it here. 03:40

6 Q. Okay. You see on the first page there 03:40

7 it says probably equals more likely than not? 03:40

8 A. Uh-huh. 03:40

9 Q. When did you write that? 03:40

10 A. I don't recall specifically, but I'm -- 03:40

11 my suspect is it was the preparation meeting 03:40

12 before the first deposition. 03:40

13 Q. Okay. And -- 03:40

14 A. Because I was still struggling with that 03:40

15 whole concept of possible and probable. 03:40

16 Q. Well, you understand what probably 03:41

17 meant; right? 03:41

18 A. If I'm not mistaken I was told that's 03:41

19 what it was. It was a definition. These were 03:41

20 my -- my documents that I had laid out as an 03:41

21 indices in the discussion, and it was the first 03:41

22 thing I wrote on, so... 03:41

23 Q. Okay. So you wrote in your discussions 03:41

24 with Plaintiffs' counsel, that probably equals 03:41

25 more likely than not; right? 03:41

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1 A. I'm fairly confident that's what they 03:41

2 mentioned to me as the definition. 03:41

3 Q. Okay. And the very next day -- 03:41

4 A. Uh-huh 03:41

5 Q. -- you testified that you did not know 03:41

6 the difference between possibility and 03:41

7 probability? 03:41

8 A. Obviously I was still confused with 03:41

9 that. 03:41

10 Q. And in the same meeting where you wrote 03:41

11 probably equals more likely than not -- well, 03:41

12 strike that. 03:41

13 A. I -- 03:41

14 Q. Strike that. 03:41

15 A. Okay, okay. 03:41

16 Q. Look at the second page of Exhibit 107, 03:41

17 please. 03:41

18 A. Sure. 03:41

19 Q. You made a note about Exhibit M09? 03:42

20 A. Yes. 03:42

21 Q. You see that? 03:42

22 A. Yes. 03:42

23 Q. And you indicated outside of spec 98 to 03:42

24 103 percent. And then you parenthetically 03:42

25 indicated 97.1 percent. 03:42

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1 Do you see that? 03:42

2 A. I do. 03:42

3 Q. 97.1 is well within specification for 03:42

4 Digitek as approved by the FDA in the ANDA, isn't 03:42

5 it? 03:42

6 A. I don't know. I'd have to go back and 03:42

7 look at it. 03:42

8 Q. Well, didn't you -- I mean if you made a 03:42

9 note that something was out of spec. 03:42

10 A. Somebody made a statement somewhere in 03:42

11 this document whatever M09 was apparently. I'm 03:42

12 not going back and looking at it. 03:42

13 Q. I understand. 03:42

14 A. That somebody made a statement you 03:42

15 realize that what this is, is not a detailed 03:42

16 reading of these documents because the search 03:42

17 capabilities of that Crivella West I think is the 03:42

18 name of it, is abysmal, so you can't find 03:43

19 anything. So I just basically went in and said, 03:43

20 pulled up 01, skimmed it. If I saw something, you 03:43

21 know -- well, I tried to do a thumbnail summary on 03:43

22 there so later on if I needed to go pull it up, I 03:43

23 would. So -- 03:43

24 Q. Okay. 03:43

25 A. Obviously -- or maybe not obviously -- 03:43

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1 it looks as if I probably printed that one and 03:43

2 it's somewhere in the stack. 03:43

3 Q. And you acknowledge of course that -- 03:43

4 that the fact that it might -- that UDL might have 03:43

5 or Mylan might have a tighter specification says 03:43

6 nothing about whether the product is actually out 03:43

7 of specification; correct? 03:43

8 A. That's correct. 03:43

9 Q. At the end of the day, the operative 03:43

10 number with respect to whether something is in or 03:43

11 out of specification is the number the number for 03:43

12 any particular attribute set forth in the ANDA; is 03:43

13 that right? 03:44

14 A. The approved application; that's 03:44

15 correct. 03:44

16 Q. Okay. So if you make a product and it's 03:44

17 distributed by somebody else and they, the 03:44

18 distributor prefers tighter specifications, that 03:44

19 doesn't have any bearing on whether the product 03:44

20 you make is actually out of specification, does 03:44

21 it? 03:44

22 A. Tighter specs are always around. 03:44

23 Q. Okay. 03:44

24 A. It's an additional level of control. 03:44

25 Q. And if they had tighter specs and the 03:44

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1 product doesn't meet them but still falls within 03:44  
2 the ANDA specifications, that product is within 03:44  
3 specification; right? 03:44

4 A. For the manufacturing service. 03:44

5 Q. Yes. 03:44

6 A. In this particular case. UDL probably 03:44  
7 would have rejected it because that's their spec. 03:44

8 Q. Fair enough, but with respect to that -- 03:44

9 A. The original ap., yes. 03:44

10 Q. And with respect to whether it is out of 03:44  
11 spec, out of specification in the eyes of the FDA, 03:44  
12 it is not out of specification; correct? 03:44

13 A. I would say that's a fair statement, 03:44  
14 yes. 03:44

15 Q. Okay. Can you look at the page that 03:44  
16 refers to Exhibit M44, please? 03:45

17 A. Sure, yes. 03:45

18 Q. Did you -- do you recall enough about 03:45  
19 M44 from looking at this document to know whether 03:45  
20 you read it or not? 03:46

21 A. I don't. 03:46

22 Q. Okay. Your thumbnail sketch as you 03:46  
23 described it indicates this is an e-mail from Sue 03:46  
24 Powers to Chuck Kuhn, regarding the recall costs 03:46  
25 for UDL. 03:46

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1 Do you see that? 03:46

2 A. I do. 03:46

3 Q. You wrote that; right? 03:46

4 A. Yes. 03:46

5 Q. All right. So that's some brief 03:46

6 characterization of what you saw when you read 03:46

7 that document? 03:46

8 A. I scanned it. I didn't read it, I 03:46

9 scanned it. 03:46

10 Q. Do the costs of a recall have anything 03:46

11 to do with whether there's adulterated or out of 03:46

12 specification product in the market? 03:46

13 A. I don't believe so. 03:46

14 Q. Look at the page of Exhibit 107 that 03:46

15 refers to M56, please. 03:47

16 A. 56? 03:47

17 Q. Yes, please. 03:47

18 A. Uh-huh. 03:47

19 Q. Do you see your handwritten note about 03:47

20 that? 03:47

21 A. I do. 03:47

22 Q. And it says that UDL to file from Lee 03:47

23 Roedke, 16 September, 2006, Activis warning 03:47

24 letter, Little Falls, New Jersey. Did I read that 03:47

25 correctly so far? 03:47

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1 A. What did you say? 03:47

2 Q. UDL to file from Lee Roedke, 16 03:47

3 September, abbreviated, 2006? 03:47

4 A. Uh-huh. 03:47

5 Q. Activis warning letter, Little Falls, 03:47

6 New Jersey. Did I read that correctly so far? 03:47

7 A. Yes. 03:47

8 Q. It goes on to say not addressing FDA ADE 03:47

9 concerns. Did I read that correctly? 03:47

10 A. Yes. 03:47

11 Q. And ADE concerns in that context is an 03:47

12 acronym for adverse drug events; correct? 03:48

13 A. Without specifically pulling it up, I 03:48

14 would say yes, that's true. 03:48

15 Q. Okay. Do you use ADE for any other 03:48

16 purpose in the context of performing your GMP 03:48

17 compliance consulting services? 03:48

18 A. No. But like you said, I'm not an 03:48

19 adverse drug event person. 03:48

20 Q. This is your terminology. 03:48

21 A. This is a summary. 03:48

22 Q. I understand. 03:48

23 A. And, again, unless we pull it up, that 03:48

24 may be what they refer to it as in the e-mail. 03:48

25 Chances are that's what it is. 03:48

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1 Q. But you made the note. 03:48

2 A. Yes. 03:48

3 Q. Do you mean to use the term ADE to stand 03:48

4 for adverse drug event? 03:48

5 A. More than likely, yes. 03:48

6 Q. Okay. 03:48

7 A. Uh-huh. 03:48

8 Q. I'm handing you, Dr. Bliesner, a 03:48

9 document that has been marked as Defendant's 03:48

10 Exhibit 87. 03:48

11 A. Okay. 03:48

12 Q. Take a moment please and review that 03:48

13 document very briefly. 03:48

14 A. Uh-huh. 03:48

15 Q. Let me know when you have reviewed it. 03:48

16 A. Sure. Okay. 03:49

17 Q. Have you seen that document before? 03:49

18 A. I'm not sure. 03:49

19 Q. All right. Well you see that -- that it 03:49

20 is referencing a warning letter -- 03:49

21 A. Uh-huh. 03:49

22 Q. -- issued to Activis in August of 2006. 03:49

23 A. Uh-huh. 03:49

24 Q. That relates to adverse drug 03:49

25 experiences. Do you see that? 03:50



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1 A. I do. 03:50

2 Q. And this is the warning letter that you 03:50

3 referred to earlier when you were talking about 03:50

4 the reports and the ADE, and we talked for a 03:50

5 moment about the connection, whether there's 03:50

6 reliability in ADE reporting, and all that. It's 03:50

7 the same point. 03:50

8 A. I'll take your word. 03:50

9 Q. So in this letter, the FDA accepts the 03:50

10 corrective actions Activis has proposed and 03:50

11 implemented with respect to that warning letter; 03:50

12 right? 03:50

13 A. Correct. 03:50

14 Q. Okay. So when you wrote in response to 03:50

15 or in connection with Exhibit M56 that Activis 03:50

16 wasn't addressing the ADE concerns, is that 03:50

17 accurate? 03:50

18 A. It's what's in the e-mail more than 03:50

19 likely -- or memo, whatever it is. 03:50

20 Q. Okay. 03:50

21 A. It's somebody, whoever that individual 03:50

22 was. 03:50

23 Q. Lee Roedke. 03:50

24 A. Apparently that's who it was. Again 03:50

25 this is a snapshot summary, glancing it at this. 03:51

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1 Whether it's an e-mail, memo or whatever. 03:51

2 Q. Okay. 03:51

3 A. That's their concern I'm assuming, not 03:51

4 going back and pulling it out. 03:51

5 Q. Okay. Well -- 03:51

6 A. Knee deep in paper. 03:51

7 Q. Yeah. Unfortunately that's a necessary 03:51

8 part of this process, Dr. Bliesner. All right. 03:51

9 Find 108, please. 03:51

10 A. Which one are we on, sir? 03:51

11 Q. Exhibit 108. 03:51

12 A. Exhibit 108. Yes, sir. 03:51

13 Q. What do you mean when you use the term 03:52

14 "blend uniformity failure." To you, what does 03:52

15 that mean? 03:52

16 A. Blend uniformity failure? 03:52

17 Q. Yeah. 03:52

18 A. It means that blend gets sampled and 03:52

19 tested wouldn't necessarily, does not have the, 03:52

20 you know, assay value that it was supposed to 03:52

21 have. 03:52

22 Q. At what point of the sampling and 03:52

23 testing process does something become a blend 03:52

24 uniformity failure? 03:52

25 A. Well, there's a spec for blend 03:52

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1 uniformity test. 03:52

2 Q. So by that you mean that you take a 03:52

3 sample of the blend, you conduct a chemical test 03:52

4 on it to determine the assay of that sample, and 03:53

5 then you apply the specifications to determine 03:53

6 whether that sample -- whether the assay value for 03:53

7 that sample is within those specifications; 03:53

8 correct? 03:53

9 A. That's a fair assessment. 03:53

10 Q. And so when you sample blends for 03:53

11 testing to determine whether it is uniformly 03:53

12 distributed -- excuse me -- most manufacturers 03:53

13 take samples of blend in duplicate or triplicate; 03:53

14 correct? 03:53

15 A. Most manufacturers? I don't know if I 03:53

16 can speak to most manufacturers, but there's more 03:53

17 than one. 03:53

18 Q. Okay. So it's not uncommon for a 03:53

19 pharmaceutical manufacturer to take blend samples 03:53

20 in duplicate or triplicate; right? 03:53

21 A. I would say that's fair. 03:53

22 Q. And that is an acceptable practice so 03:53

23 long as you, the manufacturer, have an 03:54

24 appropriately drafted SOP? 03:54

25 A. Manufacturer, during process validation 03:54

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1 will come up with a sampling plan, and a sampling 03:54  
2 approach. Manufacturing does the sampling and 03:54  
3 delivers the sample for you. 03:54

4 Q. So it is acceptable to draft a sampling 03:54  
5 plan with respect to blend sampling that calls for 03:54  
6 blend samples to be taken in duplicate or 03:54  
7 triplicate; right? 03:54

8 A. At least, yes. 03:54

9 Q. And it is acceptable to draft a testing 03:54  
10 plan. 03:54

11 A. Yes. 03:54

12 Q. For blend samples that allows for 03:54  
13 testing the second or third sample from a given 03:54  
14 location under appropriate circumstances; right? 03:54

15 A. Content uniformity, yeah, under 03:54  
16 appropriate circumstances. 03:54

17 Q. Well, so -- so it is -- you've seen and 03:55  
18 it is okay to have a sampling plan that says you 03:55  
19 take blend samples in triplicate, for example. 03:55

20 A. Uh-huh. 03:55

21 Q. You test the first sample from each 03:55  
22 location and in appropriate circumstances if -- if 03:55  
23 one of those samples is not tested within 03:55  
24 specification, you may test the second sample from 03:55  
25 that location. 03:55

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1 A. Same location. I would say it's a fair 03:55

2 statement if it's in the protocol. 03:55

3 Q. If it's in the protocol. 03:55

4 A. Yes. 03:55

5 Q. And you have to have the circumstances 03:55

6 that are called for by the protocol and that allow 03:55

7 you to test that second sample; right? 03:55

8 A. Yes 03:55

9 Q. And you have to do an appropriate 03:55

10 inspection or investigation and try to determine 03:55

11 why the first sample tested out of specification; 03:56

12 correct? 03:56

13 A. Correct. Just for content uniformity 03:56

14 for finished products, yes. 03:56

15 Q. If you have an initial sample of the 03:56

16 triplicate sample that tests out of specification, 03:56

17 do you call that a blend failure? 03:56

18 A. Do you want to say that again? 03:56

19 MR. ANDERTON: Phil, would you read it 03:56

20 back? 03:56

21 (Whereupon, the testimony was read 03:56

22 back by the court reporter, as recorded above) 03:56

23 THE WITNESS: Potentially. 03:56

24 BY MR. ANDERTON: 03:56

25 Q. Potentially. 03:56

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1 A. Yes. 03:56

2 Q. But if you have a protocol that allows 03:56

3 you to test the second or third sample after 03:56

4 conducting an appropriate investigation and after 03:56

5 following the protocol properly -- 03:56

6 A. Uh-huh. 03:56

7 Q. -- that first out of specification 03:56

8 result is not a blend failure, am I correct? 03:56

9 A. If it meets the protocol, that is 03:56

10 correct. 03:56

11 Q. Okay. So you wouldn't call it a blend 03:56

12 failure until you've run all the way to the end of 03:57

13 the protocol -- 03:57

14 A. Huh-huh. 03:57

15 Q. -- is the way I'll describe that to you; 03:57

16 is that correct? 03:57

17 A. That's a fair way to put it. 03:57

18 Q. Okay. Which might mean in certain 03:57

19 circumstances until you've tested the third of the 03:57

20 triplicate samples from one or more locations; 03:57

21 right? 03:57

22 A. Yes. 03:57

23 Q. When you use the term -- and looking at 03:57

24 Exhibit 108. 03:57

25 A. Yes. 03:57

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1 Q. Well, hold on one second. 03:57

2 MS. DREWES: I don't want to interrupt, 03:57

3 but on that hard drive that you -- that the 03:57

4 witness gave, is it okay with everyone if we 03:57

5 give everyone a CD attached with the documents 03:57

6 rather than a hard copy? Because apparently 03:57

7 you can't read them when they were printing. 03:57

8 MR. ANDERTON: Yeah, that's acceptable to 03:58

9 me. Mike, are you all right with that? 03:58

10 MR. KERENSKY: Your voice was too faint 03:58

11 for to me to hear your comment, ma'am. 03:58

12 MS. DREWES: Would the hard drive that 03:58

13 Dr. Bliesner gave us earlier, today, the -- we 03:58

14 can print the -- we can print the documents 03:58

15 but they are not legible, some of them, when 03:58

16 we print them. For some reason they come out 03:58

17 really dark is what I'm told. 03:58

18 So if we can just give everyone a disc if 03:58

19 that's agreeable to you. 03:58

20 MR. ANDERTON: Are you okay with that, 03:58

21 Mike? 03:58

22 MS. DREWES: Apparently you can read it 03:58

23 on the disc or on the computer screen. 03:58

24 MR. KERENSKY: Just as long as a general, 03:58

25 average, normal, everyday computer will open 03:58

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1           it, I'm happy. 03:58

2                   MR. ANDERTON: Well, that's just 03:58

3           described my unit, so. 03:58

4   BY MR. ANDERTON: 03:58

5           Q.     And then Dr. Bliesner, continuing on 03:58

6           with this line of questioning, if you -- again if 03:58

7           your protocol is appropriately drafted and you 03:59

8           follow that factual progression that I just 03:59

9           described, where you take samples of a blend and 03:59

10          you test the first sample from a location and it 03:59

11          is out of specification, then you follow the 03:59

12          protocol and that results in you testing then the 03:59

13          second sample from that location and it is within 03:59

14          specification, it's okay to release that batch; 03:59

15          right? 03:59

16          A.     If you're meeting your protocol. 03:59

17          Q.     If you have a protocol that allows for 03:59

18          all of that, specifies it, and if you comply with 03:59

19          it along the way; correct? 03:59

20          A.     That's a reasonable statement. 03:59

21          Q.     It's okay to release that batch? 03:59

22          A.     That blend, sure. 03:59

23          Q.     That -- 03:59

24          A.     Final blend in this case. 03:59

25          Q.     That initial I guess then -- correct. 03:59



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1 So let me ask it another way. 03:59

2 That initial out-of-specification result 04:00

3 doesn't require that the entire blend and 04:00

4 therefore the entire batch be rejected. 04:00

5 A. Not necessarily. 04:00

6 Q. Okay. 04:00

7 A. It may be, you know, extraordinary 04:00

8 circumstances where it comes in at 25 percent of 04:00

9 assay or whatever, then it's a whole different 04:00

10 bailiwick. 04:00

11 Q. Then your -- well, then your 04:00

12 investigation your protocol provides for probably 04:00

13 is going to reveal something other than just a 04:00

14 single out-of-specification result? 04:00

15 A. More than likely, yes. 04:00

16 Q. Okay. 04:00

17 MR. KERENSKY: Are you guys still there? 04:00

18 MR. ANDERTON: Yeah, we are here. 04:00

19 MR. KERENSKY: Man, you got quiet. I 04:00

20 thought you hung up on me. 04:00

21 BY MR. ANDERTON: 04:00

22 Q. Dr. Bliesner, when you did your paper 04:00

23 audit of -- of this -- of Activis to prepare your 04:00

24 report -- paper audit is your term not mine -- did 04:01

25 you ask for and did you receive the SOP of Activis 04:01

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1 Totowa that provides the protocol for testing 04:01

2 blend samples and retesting second or third 04:01

3 samples if you have an initial 04:01

4 out-of-specification result? 04:01

5 A. I don't think I specifically asked for 04:01

6 that SOP. I remember reviewing an investigation 04:01

7 having to do with blend uniformity failure. 04:01

8 Q. If you didn't ask for it, does that mean 04:01

9 you didn't review it either? 04:01

10 A. I don't know if I could say that. I'd 04:01

11 have to go back and look at the paper at I 04:01

12 reviewed. 04:01

13 Q. Okay. 04:01

14 A. With respect to that investigation. 04:01

15 Q. The documents -- well, the documents 04:01

16 that you reviewed -- 04:02

17 A. Uh-huh. 04:02

18 Q. -- are set forth in your report; right? 04:02

19 A. They should be, yes. 04:02

20 Q. So if you reviewed it, our review of 04:02

21 those documents will reveal that you reviewed it? 04:02

22 A. That I reviewed it, yes. 04:02

23 Q. Right. 04:02

24 A. That's a fair statement. 04:02

25 Q. So if it's not listed among the 04:02

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1 documents that you reviewed -- if it's not listed 04:02  
2 in your report, it's not something you reviewed? 04:02  
3 A. Not necessarily. 04:02  
4 Q. Pardon? 04:02  
5 A. They're not mutually exclusive, most of 04:02  
6 it because of all the volume of documents here. 04:02  
7 It obviously didn't include every single one that 04:02  
8 I reviewed, just ones that I felt had pertinent 04:02  
9 points with respect to this. 04:02  
10 Q. If it's not listed in your report -- 04:02  
11 A. Yes. 04:02  
12 Q. -- is it fair to say that you didn't 04:02  
13 place any significance on it and didn't rely on it 04:02  
14 in drafting your report? 04:02  
15 A. I didn't rely on it. I don't know if 04:02  
16 significance is a word that I would use. 04:02  
17 Q. How are we to know or to identify if I 04:03  
18 asked you right now whether you reviewed this SOP 04:03  
19 -- 04:03  
20 A. Uh-huh 04:03  
21 Q. -- and it's not listed in your report -- 04:03  
22 A. That's right. 04:03  
23 Q. -- how would you know? 04:03  
24 A. It's not listed in the report. I'd go 04:03  
25 through this index and see if I popped it up. 04:03

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1 Q. And if it's not in this index? 04:03

2 A. And it's not in the supplemental 04:03

3 documents that were sent to me by -- then chances 04:03

4 are I didn't review it. 04:03

5 Q. Okay. 04:03

6 I'm going to hand you a document that has been 04:03

7 marked as -- well, what's it say on there? 04:03

8 A. 58. 04:03

9 Q. 58? 04:04

10 A. Yeah. 04:04

11 MR. ANDERTON: Plaintiffs' Exhibit 58. 04:04

12 Plaintiffs', Mike. 04:04

13 MR. KERENSKY: Got it. 04:04

14 BY MR. ANDERTON: 04:04

15 Q. Have you seen that before, Dr. Bliesner? 04:04

16 A. Isn't this one that we -- the 483s that 04:04

17 were included before? Can I take a look at the 04:04

18 report? I'm pretty sure that I have, but I just 04:04

19 want to make sure. 04:04

20 Q. Well, if you didn't look at this, you 04:04

21 don't have a report. 04:04

22 A. Okay. 04:04

23 Q. But you may do whatever you like to 04:04

24 satisfy yourself, but I guess I can shortcircuit 04:04

25 that. 04:04

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1 A. Okay. Please. 04:04

2 Q. Well, I'm here to help, Dr. Bliesner. 04:04

3 Sarah will tell you I'm a giver. 04:05

4 MS. DREWES: Oh, yeah. Big time. 04:05

5 MR. KERENSKY: Note the snickers on the 04:05

6 phone. 04:05

7 MR. ANDERTON: I'm sorry. Defense 04:05

8 Exhibit 58, Mike. I misspoke earlier. 04:05

9 MR. KERENSKY: About you being a giving 04:05

10 person? 04:05

11 MS. DREWES: Yeah, but got also about the 04:05

12 exhibit. 04:05

13 MR. KERENSKY: That you are here to 04:05

14 help? You're not with the IRS. 04:05

15 MR. ANDERTON: It's Defendant's Exhibit 04:05

16 58. 04:05

17 MR. KERENSKY: Thank you. 04:05

18 MR. ANDERTON: It's Plaintiffs' Exhibit 04:05

19 90, I believe. No. Not true. 04:05

20 BY MR. ANDERTON: 04:05

21 Q. Dr. Bliesner, did you review this or 04:05

22 not. What do you think? 04:06

23 A. Yes. 04:09

24 Q. What page of your report are you looking 04:09

25 at? 04:09

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1	A.	47.	04:09
2	Q.	What reference?	04:09
3	A.	A37.	04:09
4	Q.	Well?	04:09
5	A.	By the look of it.	04:09
6	Q.	That's an EIR, not a 483.	04:09
7	A.	It is the EIR that had the 483s in	04:09
8		them. I misspoke. I'm sorry.	04:09
9	Q.	So you didn't review this apparently?	04:09
10	A.	The 483s stand-alone?	04:09
11	Q.	Yes.	04:09
12	A.	No, it would be the EIR.	04:09
13	Q.	So that's Exhibit 91. You agree with	04:09
14		that; right?	04:10
15	A.	Yes.	04:10
16	Q.	All right. I'm going to hand you a copy	04:10
17		of Exhibit 91.	04:10
18	A.	Okay.	04:10
19	Q.	So that we do this and keep you as	04:10
20		comfortable as you need to be. I'm here for your	04:10
21		comfort.	04:10
22		I would like you to first look at the document	04:10
23		I just handed you and tell me if you reviewed that	04:10
24		document.	04:10
25	A.	91. Plaintiffs' Exhibit 91, yes, sir.	04:10

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1 Q. Okay. Turn to page 43 of that document. 04:10

2 A. May have a second, please? I want to 04:10

3 make sure that I -- because there were some of 04:10

4 these reports that didn't necessarily have all of 04:11

5 the pages that came with them, the EIR. There was 04:11

6 one circumstance that I recall that didn't. So I 04:11

7 want to make sure that what I've got over here is 04:11

8 the same and inclusive. 04:11

9 Q. Okay. 04:11

10 A. Okay. Is that fair? 04:11

11 Q. Well, I guess I would hope that you 04:11

12 would have noted in your report when you reviewed 04:11

13 a document that was incomplete, but you didn't do 04:11

14 that with respect to this document. 04:11

15 A. I just want to look at it. 04:11

16 Q. Of course you do. 04:11

17 THE VIDEOGRAPHER: While he's doing that, 04:11

18 you have five minutes left on the tape. 04:11

19 MR. ANDERTON: Let's go off the record 04:11

20 and change the tape. 04:11

21 THE WITNESS: The time is 4:13 p.m. 04:11

22 We're going off the record. 04:11

23 (Short break) 04:21

24 THE VIDEOGRAPHER: The time is 4:24 p.m. 04:21

25 We are on the record. This is the beginning 04:22

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1 of tape eight. 04:22

2 BY MR. ANDERTON: 04:22

3 Q. Dr. Bliesner, are you all set? 04:22

4 A. Yes, sir. 04:22

5 Q. Okay. I want to ask you -- 04:22

6 Dr. Bliesner, I'm going to go away from that 04:23

7 document for just a moment and ask you a general 04:23

8 question. 04:23

9 A. Okay. 04:23

10 Q. You are a chemist by trade; right? 04:23

11 A. I am a Ph.D. and analytical chemist by 04:23

12 training. 04:23

13 Q. Does that mean the answer to my question 04:23

14 is yes? 04:23

15 A. Chemist? Yes. Sorry. There are many 04:23

16 flavors of chemists. That's why. 04:24

17 Q. I understand, but above all else as a 04:24

18 matter of fact you call yourself a chemist? 04:24

19 A. A research chemist, yes, I do. 04:24

20 Q. When testing a tablet and particularly a 04:24

21 solid oral dose tablet for potency -- 04:24

22 A. Uh-huh. 04:24

23 Q. -- what method would you use if you 04:24

24 could use any method you wanted? 04:24

25 A. Not to sound cryptic, but it depends on 04:24



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1 the dosage form and what the characteristics are 04:24  
2 and what it's amenable to as far as analysis 04:24  
3 goes. 04:24

4 Q. What do you mean by that? 04:24

5 A. Well, it turns out that certain 04:24  
6 compounds might not be appropriately soluble let's 04:24  
7 say and therefore easily dissolved and injected 04:24  
8 into an HPLC system let's say. 04:24

9 Q. Did you review the ANDA for Digoxin and 04:24  
10 particularly for the Digitek version of Digoxin 04:25  
11 tablets manufactured by Amide and then Activis 04:25  
12 sufficiently to allow you to have an opinion about 04:25  
13 which methods could be used to examine the potency 04:25  
14 of a tablet -- of one of those tablets? 04:25

15 A. I'm sorry. Go again. 04:25

16 MR. ANDERTON: Phil, can you get that? I 04:25  
17 did it very methodically. I would like 04:25  
18 Dr. Bliesner to hear that. I think I got it 04:25  
19 right. 04:25

20 THE WITNESS: If I recall, I didn't get 04:26  
21 an opportunity to read all of the ANDA 04:26  
22 sections because I think that they were all 04:26  
23 available to me at the time of review. Just 04:26  
24 to put that in perspective. 04:26

25 As far as being able to assess whether -- 04:26

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1 I guess the question is assess whether the 04:26

2 methods are appropriate for use? 04:26

3 BY MR. ANDERTON: 04:26

4 Q. No. Do you have an opinion about -- 04:26

5 about which of those -- which of the available 04:26

6 methods to test a tablet for potency could be 04:26

7 used? 04:26

8 A. Could be used with -- HPLC is a method 04:26

9 of choice. 04:26

10 Q. Okay. 04:26

11 A. If I'm not mistaken, having looking at 04:26

12 the 484 stuff, those were HPLC methods for assays 04:26

13 and related compounds. 04:26

14 Q. And the Activis analytical method was 04:26

15 also HPLC methods; correct? 04:26

16 A. I'm pretty sure yes, yes. 04:27

17 Q. So unless nobody knew what they were 04:27

18 doing, HPLC was an acceptable method to test this 04:27

19 compound; correct? 04:27

20 A. For assay. 04:27

21 Q. For assay. 04:27

22 A. Correct. 04:27

23 Q. Well, and to go back to the term I used, 04:27

24 for potency. 04:27

25 A. Yes. Assay, potency, same thing. 04:27

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1 Q. Okay. What about single point UV? How 04:27  
2 does that compare to HPLC as a test method to test 04:27  
3 the potency of a tablet and specifically of one of 04:27  
4 these Digitek Digoxin tablets? 04:27  
5 A. Single point UV? 04:27  
6 Q. Yes. 04:27  
7 A. How would it compare? It depends 04:27  
8 because LC is a separations technique that 04:27  
9 separates out any potential interference from the 04:27  
10 main component so you get an assay. An HPLC 04:27  
11 system essentially a UV system at the end. The 04:27  
12 detector for HPLC is just a UV. But in this case 04:28  
13 it is has, if you will, as an analogy, the HPLC is 04:28  
14 a means of preparing the sample so you're looking 04:28  
15 at a single component when it goes into the UV 04:28  
16 detector; okay? If you have -- it is possible 04:28  
17 with a product to develop and validate a method, 04:28  
18 single point UV method if there are no 04:28  
19 interferences. 04:28  
20 Q. If somebody sent you a sample -- 04:28  
21 A. Uh-huh. 04:28  
22 Q. -- and said Dr. Bliesner, chemist -- 04:28  
23 Ph.D. Chemist Bliesner, we'd like you to examine 04:28  
24 this tablet for potency. 04:28  
25 A. Uh-huh. 04:28

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1 Q. How would you compare the reliability of 04:28  
2 results of a test conducted using single point UV 04:28  
3 versus a test using HPLC? 04:29

4 A. How would you compare? 04:29

5 Q. How would you compare? Not literally 04:29  
6 how would you put them side by side and compare. 04:29  
7 How would you characterize the differences between 04:29  
8 results reached using single point UV versus the 04:29  
9 results reached using HPLC. Is one more reliable 04:29  
10 than the other? 04:29

11 A. Not necessarily. It depends on whether 04:29  
12 there are interference issues. You've got to 04:29  
13 realize that HPLC with a UV detector is a single 04:29  
14 point UV detection, just like you put it into a UV 04:29  
15 spectrometer. Same thing. It's only a single 04:29  
16 point. 04:29

17 Q. So you need to know more about the 04:29  
18 circumstances before you would be able to -- 04:29

19 A. Absolutely. Sure. 04:29

20 Q. Be able to compare the reliability of 04:29  
21 outcomes for -- 04:29

22 A. Right. 04:29

23 Q. -- those two tests. 04:29

24 A. For instance, they do dissolution 04:29  
25 testing. And the dissolution method is UV, but 04:29

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1 there is a whole -- if I recall correctly, pulling 04:29  
2 off memory -- there is a derivatization and things 04:30  
3 that like that with respect to the UV because that 04:30  
4 would suggest that there are potential 04:30  
5 interferences. And derivatization and looking at 04:30  
6 it in the means that they did would suggest -- not 04:30  
7 having looked at the validation -- that they were 04:30  
8 able to get around interferences in that fashion. 04:30  
9 Q. Just to be clear with respect to 04:30  
10 Activis, are the entirety of your opinions in this 04:30  
11 case set forth in the report you've issued? Do 04:31  
12 you have any supplemental or additional opinions 04:31  
13 with respect to Activis? 04:31  
14 A. I don't believe so. 04:31  
15 Q. Well, you don't believe so or you don't? 04:31  
16 A. It's a broad statement. 04:31  
17 Q. I need this question to be answered 04:31  
18 definitively, Dr. Bliesner. It's a very important 04:31  
19 question. 04:31  
20 A. Additional, post-the-report? 04:31  
21 Q. Yes. 04:31  
22 A. In the report? 04:31  
23 Q. Yeah, you have issued a report in this 04:31  
24 case -- 04:31  
25 A. Yes. 04:31

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1 Q. -- that we've been told contains your 04:31

2 opinions -- 04:31

3 A. Yes. 04:31

4 Q. -- about Activis. And there was some 04:31

5 exchange last time about whether you had an 04:31

6 opinion about Mylan or didn't have an opinion and 04:31

7 we got a representation from Plaintiffs' counsel 04:31

8 about that, and that issue is done and resolved as 04:31

9 far as we're concerned. 04:31

10 A. Okay. 04:31

11 Q. So I'm asking you now strictly about 04:31

12 Activis and the opinions that are set forth in 04:32

13 your June 15, 2010, report. 04:32

14 A. Yes. 04:32

15 Q. About Activis. 04:32

16 A. Yes. 04:32

17 Q. Do they -- do they comprise the entirety 04:32

18 of your opinions about Activis in this case? 04:32

19 A. That's a fair statement, yes. 04:32

20 Q. Yes, they do? 04:32

21 A. Uh-huh. 04:32

22 Q. You need to say that. 04:32

23 A. Yes, they do. 04:32

24 Q. Okay. So there are no supplemental 04:32

25 opinions about Activis that are not contained in 04:32

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1 your report? 04:32

2 A. I've not reviewed any documentation or 04:32

3 anything else that would supplement what I've 04:32

4 written in the report. 04:32

5 Q. So again need this answered my way. You 04:32

6 don't have any supplemental opinions about Activis 04:32

7 that are not contained in this report; is that a 04:32

8 correct statement? 04:32

9 A. That is a correct statement. 04:33

10 Q. Thank you. 04:33

11 So the process -- well, you -- the product 04:33

12 that was in the market and subject to recall you 04:33

13 know was .125 and .25 milligram Digitek. You are 04:33

14 aware of that; right? 04:33

15 A. Yes, sir. 04:33

16 Q. Two dose strengths; right? 04:33

17 A. Yes, sir. 04:33

18 Q. And both processes were validated; 04:33

19 correct? 04:33

20 A. I have not seen the process validation 04:33

21 reports so I can't say definitively, but because 04:34

22 they're in the application and it was approved, 04:34

23 one would extrapolate that they were validated. 04:34

24 Q. Any reason to believe that either 04:34

25 process was not validated? 04:34

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1	A.	No.	04:34
2	Q.	And I believe you testified last time	04:34
3		that you're not an expert in process validation	04:34
4		but that you certainly support -- I believe those	04:34
5		were your words.	04:34
6	A.	Yes.	04:34
7	Q.	From an -- I forget what perspective you	04:34
8		said.	04:34
9	A.	Cross-functional and analytical	04:34
10		development testing, troubleshooting.	04:34
11	Q.	That's a fancy way of saying you	04:34
12		recognize the value and importance of process	04:34
13		validation.	04:34
14	A.	I absolutely, yeah.	04:34
15	Q.	Okay.	04:34
16	A.	It's a very critical component to the	04:34
17		whole application development.	04:34
18	Q.	It's kind of a jumping off point for	04:34
19		everything, isn't it?	04:34
20	A.	Process validation?	04:34
21	Q.	Yes.	04:34
22	A.	Jumping off point?	04:34
23	Q.	Well, with respect actually producing	04:34
24		and manufacturing a drug product.	04:34
25	A.	Uh-huh.	04:34



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1 Q. You must first develop and validate a 04:34  
2 process for doing that; correct? 04:35

3 A. If you need to develop and validate -- 04:35  
4 develop a dosage form, a formulation and then to a 04:35  
5 small scale move it into process validation, 04:35  
6 that's correct. 04:35

7 Q. Okay. So once you have a formulation 04:35  
8 developed -- 04:35

9 A. Yes. 04:35

10 Q. -- the next step is to develop and 04:35  
11 validate the process; right? 04:35

12 A. Scale up first and then validate. 04:35

13 Q. Okay. So let's make that the not the 04:35  
14 next immediate step after developing the 04:35  
15 formulation but two steps later is a process 04:35  
16 validation. And you cannot go forward with 04:35  
17 manufacturing any drug product without a validated 04:35  
18 process; is that correct? 04:35

19 A. That's correct. 04:35

20 Q. The FDA would not approve either an NDA 04:35  
21 or an ANDA without demonstration of a validated 04:35  
22 process; correct? 04:35

23 A. And the demonstration would be for 04:35  
24 instance in the ANDA III production run. 04:35

25 Q. Understood. 04:35

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1 A. That's the output of process validation 04:35

2 specifically requiring, you know, a validation, 04:36

3 reported development on the application, that 04:36

4 isn't necessarily the case. 04:36

5 Q. In whatever form, you must prove to the 04:36

6 FDA -- 04:36

7 A. Uh-huh. 04:36

8 Q. -- that you have developed and validated 04:36

9 your process before they will approve your 04:36

10 application. 04:36

11 A. Yes. 04:36

12 Q. Is that correct? 04:36

13 A. That is correct. 04:36

14 Q. All right. And a process validation 04:36

15 tells you that you have developed a process that 04:36

16 allows you to consistently manufacture product 04:36

17 within specification; right? 04:36

18 A. Within the operating parameters of the 04:36

19 equipment; correct. 04:36

20 Q. Understood. 04:36

21 A. Uh-huh. 04:36

22 Q. And as you move forward from your 04:36

23 process validation, there are various things that 04:36

24 speak to or that confirm the conclusions reached 04:36

25 in your process validation study, one of which is 04:36

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1 manufacturing product within specification over 04:37  
2 time; correct? 04:37

3 A. That's one aspect; correct. You also 04:37  
4 monitor complaints, returns, you know, 04:37  
5 investigations, that come up during the course of 04:37  
6 the manufacturing. Lots of different things. 04:37

7 Q. Understood. 04:37

8 You continue to monitor the things that might 04:37  
9 call into question the validation of your process; 04:37  
10 right? 04:37

11 A. That's correct. Because in my 04:37  
12 experience when you go from scale up to 04:37  
13 manufacturing, invariably as you gain experience 04:37  
14 with the product there, you'll find things that 04:37  
15 are potentially difficult. 04:37

16 Q. And finding things that are potential 04:37  
17 difficulties, to use your words? 04:37

18 A. Uh-huh. 04:37

19 Q. That doesn't mean your process is 04:37  
20 invalidated. It means you need to investigate and 04:37  
21 determine whether they require an adjustment of 04:37  
22 your process; right? 04:38

23 A. That's open to interpretation. It 04:38  
24 really is. And the agency, you know, in one 04:38  
25 circumstance may say your process is out of 04:38

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1 control, it's invalidated, but in another 04:38

2 circumstance the same people within the same 04:38

3 division may say, you know, it's okay. You need 04:38

4 to put in some additional controls. So it's open 04:38

5 to interpretation. 04:38

6 Q. What weight do you give -- in validating 04:38

7 as you're undertaking a consulting engagement -- 04:38

8 A. Uh-huh. 04:38

9 Q. -- and evaluating whether your client 04:38

10 has or is achieving GMP compliance? 04:38

11 A. Uh-huh. 04:38

12 Q. What weight do you give to the fact that 04:38

13 the client has a validated process followed by 04:38

14 years and years and production of literally 04:38

15 billions and billions of tablets that were within 04:38

16 specification? 04:39

17 A. I'm sorry. It was a long one, so -- 04:39

18 MR. ANDERTON: Please read it back. 04:39

19 (Whereupon, the testimony was read 04:39

20 back by the court reporter, as recorded above) 04:39

21 THE WITNESS: That's obviously an 04:39

22 important part of the picture. 04:39

23 BY MR. ANDERTON: 04:39

24 Q. Okay. 04:39

25 A. Supporting process validation and 04:39

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1 showing you're in control. 04:39

2 Q. Okay. So that is a significant fact 04:39

3 that -- as you did an evaluation of circumstances 04:39

4 that met those -- that description, that would be 04:39

5 one piece of information that you put in, in the 04:39

6 bucket if you will, suggesting GMP compliance. 04:39

7 A. One piece. Manufacturing investigations 04:39

8 would go hand and hand with that in particular. 04:39

9 Q. Understood. But that fact that I've 04:39

10 described -- 04:40

11 A. Uh-huh. 04:40

12 Q. -- validated process and years of 04:40

13 in-specification production covering billions of 04:40

14 tablets, that would go certainly go in the -- 04:40

15 A. It would. We're assuming that the data 04:40

16 reporting capture and all that stuff is accurate. 04:40

17 Q. Understood. 04:40

18 A. Okay. That's a big assumption because 04:40

19 it isn't necessarily the case in a lot of 04:40

20 facilities. 04:40

21 Q. Okay. 04:40

22 A. Uh-huh. 04:40

23 Q. But you would only be able to determine 04:40

24 whether it was accurate if you looked at the 04:40

25 data. 04:40

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1 A. You'd have to look at the data and then 04:40  
2 confirm with individuals that are doing entry into 04:40  
3 the system, or validation of the system and 04:40  
4 whatever. 04:40  
5 Q. Understood. 04:40  
6 A. That they would hold up. I'm sorry. 04:40  
7 No. Would hold up. 04:40  
8 Q. But inherent in what you've just said -- 04:40  
9 A. Uh-huh. 04:40  
10 Q. -- is that you must look at the data in 04:40  
11 order to challenge it; correct? 04:40  
12 A. The data in a broad sense. 04:40  
13 Q. You used that term, Dr. Bliesner. 04:40  
14 A. Yes, I know. But if we are talking 04:40  
15 specific process validation, methods validation, 04:41  
16 data in general because the data can be -- I'm 04:41  
17 sorry. 04:41  
18 Q. As you used the term? 04:41  
19 A. Yes. 04:41  
20 Q. I was merely trying to ask you questions 04:41  
21 about how you -- 04:41  
22 A. Okay. 04:41  
23 Q. -- used the term? 04:41  
24 A. Okay. 04:41  
25 Q. Now, you can't use it and then say -- 04:41

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1	A.	No.	04:41
2	Q.	-- what the heck are you talking about?	04:41
3	A.	I understand.	04:41
4	Q.	Okay.	04:41
5	A.	I just want to make sure that we're on	04:41
6		all on the same page here. It's late in the day	04:41
7		and I'm not trying to be evasive.	04:41
8	Q.	I understand but as I understood your	04:41
9		answer, if you were going to question or challenge	04:41
10		the data -- you said assuming the data.	04:41
11	A.	Are valid.	04:41
12	Q.	Valid.	04:41
13	A.	Your reflection of what's reality.	04:41
14	Q.	Exactly.	04:41
15	A.	Uh-huh.	04:41
16	Q.	The only way you could determine whether	04:41
17		the data are valid is to start by looking at the	04:41
18		data. There would be other steps you perform, but	04:41
19		the first step you'd have to do is look at the	04:41
20		data, am I correct?	04:41
21	A.	That's correct.	04:41
22	Q.	Look at page 16 of your report, please.	04:42
23	A.	Yes.	04:42
24	Q.	Give me one second.	04:42
25	A.	Sure.	04:42

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1 Q. Dr. Bliesner, paragraph 39 on page 16. 04:43  
2 Do you see that? 04:43  
3 A. Yes, sir. I do. 04:43  
4 Q. There you discuss investigation into -- 04:43  
5 well, you don't identify the lot number, but -- 04:43  
6 A. No, sir. 04:43  
7 Q. But the lot that had some defectively 04:43  
8 thick tablets discovered during manufacturing. 04:43  
9 And the second to last sentence says: 04:43  
10 "Product is released to market without 04:43  
11 conclusive evidence of what caused the 04:43  
12 double-thick problem on 5 December, 2007." 04:43  
13 That's not accurate is it? 04:43  
14 A. I'd have to go back and pull up the 04:43  
15 reference to be sure. 04:43  
16 Q. Okay. Well you -- 04:43  
17 A. Because it's very -- the investigation, 04:43  
18 if I recall how it's done and how it's written, 04:43  
19 anything like that, it was stuff to pull dates 04:43  
20 together so I can't definitively say that that's 04:43  
21 an incorrect date. 04:43  
22 Q. Well there's -- if you read the 04:43  
23 investigation record, there's plenty of documents 04:43  
24 in the investigation report indicating activities 04:44  
25 occurring. In fact the 100 percent visual 04:44



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1 inspection very clearly didn't occur until January 04:44

2 2008. 04:44

3 A. Okay. 04:44

4 Q. So did you just misread that 04:44

5 investigation? 04:44

6 A. Incident report. I'm sorry. What is 04:44

7 the question? 04:44

8 Q. Did you just misread that investigative 04:44

9 report? 04:44

10 A. I don't think so. Like I said, I have 04:44

11 to go back and look at it and reconstruct it again 04:44

12 to determine if that -- your claim that that's an 04:44

13 incorrect date is incorrect. 04:44

14 Q. You made comment earlier about operators 04:44

15 or employees being unable to read or speak English 04:45

16 or cannot read English. 04:45

17 A. Uh-huh. 04:45

18 Q. What did you do to verify the accuracy 04:46

19 of that statement? 04:46

20 A. I -- if I'm not mistaken, it was in an 04:46

21 e-mail and I read the e-mail. 04:46

22 Q. So you just read the e-mail and that was 04:46

23 enough for you? 04:46

24 A. Yes. 04:46

25 Q. Okay. So you didn't do anything beyond 04:46

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1 that? 04:46

2 A. I'm not sure what I could have done 04:46

3 beyond that, quite honestly. 04:46

4 Q. Dr. Bliesner, do you understand the 04:46

5 nature of litigation? You've never been an expert 04:46

6 witness before. 04:46

7 A. I have not. 04:46

8 Q. Do you understand the general nature of 04:46

9 litigation? 04:46

10 A. The general nature of litigation? 04:46

11 Q. Yeah. 04:46

12 A. How you would define it and how I define 04:46

13 it, probably different things. 04:46

14 Q. Well, do you understand that Plaintiffs 04:46

15 are the ones who bring lawsuits and they make 04:47

16 allegations against Defendants. They allege that 04:47

17 certain things happened and in this context -- 04:47

18 pharmaceutical product liability context -- 04:47

19 Plaintiffs allege that they were harmed by 04:47

20 products; right? 04:47

21 A. That's correct, yes. 04:47

22 Q. And you understand that the lawyers for 04:47

23 the Plaintiffs are required to or are attempting 04:47

24 to prove those allegations. 04:47

25 A. That's correct, as I understand it. 04:47

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1 Q. Okay. And you understand, then, that 04:47  
2 the lawyers for the Plaintiffs as part of 04:47  
3 performing their job are going to go out and find 04:47  
4 documents that they believe support their 04:47  
5 position. 04:47

6 A. I would say that's a fair statement. It 04:48  
7 would make sense. 04:48

8 Q. Reasonably self-evident; right? 04:48

9 A. Yeah, it makes sense. 04:48

10 Q. Okay. And when you got the documents 04:48  
11 from Plaintiffs' counsel in this case, I see two 04:48  
12 primary lists of documents that you got. One is 04:48  
13 Plaintiffs' exhibits. 04:48

14 A. Uh-huh. 04:48

15 Q. And the other Mylan exhibits. 04:48

16 A. Uh-huh. 04:48

17 Q. Did it trouble you at all that you were 04:48  
18 looking only at the documents that Plaintiffs' 04:48  
19 counsel wanted to you see? 04:48

20 A. I don't think that's necessarily the way 04:48  
21 it was. In particular I asked at the start of the 04:48  
22 project for a list of -- again, go back to my 04:48  
23 report. I was serving as a consultant, and they 04:48  
24 asked me to evaluate the status of, you know, the 04:48  
25 facility in terms of manufacturing restricted to 04:48

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1 Digitek, restricted to Amide, Activis, or 04:49

2 whatever, and then they then asked me if there 04:49

3 were documents that I thought would be useful for 04:49

4 my review so I created the list and gave it to 04:49

5 them. 04:49

6 Q. You did? 04:49

7 A. Yes. 04:49

8 Q. Do we have that list? 04:49

9 A. It was given the last go around. I 04:49

10 handed it out, or it was on the disc, one of the 04:49

11 two. 04:49

12 Q. Well, the only thing you gave last go 04:49

13 around was Exhibits -- you have them there in 04:49

14 front of you, 107, 108? 04:49

15 A. Uh-huh. It may be on that hard drive. 04:49

16 It was provided. 04:49

17 Q. Okay. And when did you prepare that 04:49

18 list that you gave to Plaintiffs? 04:49

19 A. Very early on in the process. 04:49

20 Q. Did you get the documents that were on 04:49

21 that list? 04:49

22 A. Not all of them, no. 04:49

23 Q. Did that trouble you at all? 04:49

24 A. Trouble is not a word. It was a little 04:49

25 frustrating for me. 04:50

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1 Q. What didn't you get? 04:50

2 A. I would have to look at the list 04:50

3 specifically. I think like we talked about, I got 04:50

4 late yesterday evening -- was it process 04:50

5 validation report, you know, those kinds of 04:50

6 things. I know there were difficulties with the 04:50

7 system from my understanding. 04:50

8 Q. Okay. 04:50

9 A. In getting documents and they're not all 04:50

10 loaded up and that kind of stuff. 04:50

11 Q. Okay. 04:50

12 A. So. 04:50

13 Q. Well, so what didn't you get? 04:50

14 A. I would have to pull up the list. 04:50

15 Q. But there were things that you asked for 04:50

16 and didn't get. 04:50

17 A. That's correct. 04:50

18 Q. You definitely got all of the 04:50

19 Plaintiffs' exhibits, though; right? 04:50

20 A. I -- I can't say whether I got all the 04:50

21 Plaintiffs' exhibits. 04:50

22 Q. Well? 04:50

23 A. If they are all of them, I, then, yes. 04:50

24 But I don't know if that's all of them. Because 04:50

25 we -- they created as I understand -- excuse me. 04:50

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1 They created folders that individuals could look 04:50  
2 at. 04:50  
3 Q. Individual whos? I mean. 04:50  
4 A. People like myself that were reviewing 04:51  
5 documents. 04:51  
6 Q. Okay. 04:51  
7 A. And those documents that they wished me 04:51  
8 to review were placed in folders on their 04:51  
9 electronic system or they delivered them, sent, 04:51  
10 e-mail -- e-mailed them. 04:51  
11 Q. Okay. 04:51  
12 A. Uh-huh. 04:51  
13 Q. And did you understand as you conducted 04:51  
14 your paper audit that the Plaintiffs' exhibits 04:51  
15 were the documents the Plaintiffs' lawyers 04:51  
16 believed helped them? 04:51  
17 A. Actually I didn't give it any 04:51  
18 consideration. I was just doing an audit. 04:51  
19 Q. Never occurred to you? 04:51  
20 A. Actually, it did not. 04:51  
21 Q. Well, you weren't necessarily doing an 04:51  
22 audit. You were looking at the documents they 04:51  
23 selected to give you. 04:51  
24 A. I don't think that's a -- that's fair 04:51  
25 statement. 04:51

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1 Q. Is it not fair wholly or is it not fair 04:51

2 just partially. I mean you got all the documents 04:51

3 they wanted you to have but did not get the 04:51

4 documents, all of the documents you asked for. 04:51

5 A. That's a true statement. 04:51

6 Q. Okay. 04:51

7 A. And why that happened, I'm not sure. 04:52

8 Other than it was -- 04:52

9 Q. Got a guess? 04:52

10 A. No. Remember rule number one, don't 04:52

11 guess. 04:52

12 Q. I understand. I understand. 04:52

13 A. And that's what so much of this has been 04:52

14 today is that I'm trying to make sure that I'm not 04:52

15 guessing. 04:52

16 Q. I don't want you to guess. 04:52

17 A. Yes. 04:52

18 Q. But you're a sharp guy. I'm sure you 04:52

19 can figure out why it is that you got what they 04:52

20 wanted you to have but didn't get everything you 04:52

21 asked for. 04:52

22 A. I wouldn't comment on that. 04:52

23 Q. Does it trouble you at all Dr. Bliesner 04:52

24 that nobody has produced a single double-thick 04:53

25 tablet from the market from the recalled batches? 04:53

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1 fact Plaintiff told you that in your meeting 04:55

2 before your deposition. 04:55

3 A. Yes, sir. That -- 04:55

4 Q. And -- 04:55

5 A. -- a small number of a large number is 04:55

6 still substantial in my mind. 04:55

7 Q. Zero is not substantial, is it? 04:55

8 A. Just because you haven't seen anything 04:55

9 doesn't mean it's not there, especially when you 04:55

10 look at the lack of controls within that facility. 04:55

11 Q. You're relying on inferences again; 04:55

12 right? 04:55

13 A. I don't think it's inferences. 04:55

14 Q. You don't have any direct proof so it 04:55

15 must be an inference; right? 04:55

16 A. I don't think an inference. It's a mass 04:55

17 of data. I think that the thing that troubles me 04:55

18 more than anything -- I'm sorry. I'm done. 04:56

19 Q. It's a mass of data that create an 04:56

20 inference. 04:56

21 MR. KERENSKY: There you go again, Mike. 04:56

22 MR. ANDERTON: Mike, he stopped his 04:56

23 answer and said I'm done. 04:56

24 MR. KERENSKY: He took a breath. 04:56

25 MR. ANDERTON: He said -- 04:56

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1 MR. KERENSKY: And you jumped on him. 04:56  
2 Let him finish. 04:56  
3 MR. ANDERTON: Mike, he said I'm done. 04:56  
4 MR KERENSKY: Read it back. If you are 04:56  
5 right, I'll take it back. 04:56  
6 (Whereupon, the testimony was read 04:56  
7 back by the court reporter, as recorded above) 04:56  
8 Q. Are you done, Dr. Bliesner? 04:56  
9 A. On which point here? 04:56  
10 Q. Exactly. 04:56  
11 MR. KERENSKY: Let's read back what he 04:56  
12 was saying when you jumped on his sentence 04:56  
13 there. 04:56  
14 MR. ANDERTON: And I think the record 04:56  
15 clearly showed earlier that he interrupted 04:56  
16 me. I let that go. Go ahead, Phil. 04:56  
17 MR. KERENSKY: I think his last word was 04:57  
18 "and." 04:57  
19 MR. ANDERTON: No, it wasn't. 04:57  
20 MR. KERENSKY: What was the last word 04:57  
21 before you said no, no. I couldn't quite hear 04:57  
22 Phil. He was fairly far away. 04:57  
23 MR. ANDERTON: The thing that tells me 04:57  
24 more than anything. 04:57  
25 MR. KERENSKY: You don't end a sentence 04:57

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1 in anything. 04:57

2 MR. ANDERTON: Mike, the problem is, he 04:57

3 answered my question. He recognized -- 04:57

4 MR. KERENSKY: There's just disagreement. 04:57

5 MR. ANDERTON: He recognized -- Mike, he 04:57

6 recognized and stopped himself when he was 04:57

7 answering a question that hadn't been asked. 04:57

8 He did it. 04:57

9 MR. KERENSKY: Well, I don't how he could 04:57

10 be doing both, Mike. He was still talking and 04:57

11 you interrupted him. That's all there is to 04:57

12 it. 04:57

13 MR. ANDERTON: I didn't interrupt him, 04:57

14 Mike. Now, I really don't appreciate this -- 04:57

15 I mean you are telling him what to do, Mike. 04:57

16 It's inappropriate. 04:57

17 MR. KERENSKY: I'm telling you what to 04:57

18 do. Don't interrupt him. 04:58

19 MR. ANDERTON: Dr. Bliesner, are you 04:58

20 done? 04:58

21 MR. KERENSKY: Read that whole answer 04:58

22 back before Mike started talking again and 04:58

23 then ask him that question and we'll move on. 04:58

24 MR. ANDERTON: I asked him the question. 04:58

25 He stopped himself, Mike. You're not here. 04:58

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1 He put his hands up and said "I'm sorry." And 04:58  
2 he stopped and said -- 04:58  
3 MR. KERENSKY: And you started to 04:58  
4 interrupt him. 04:58  
5 MR. ANDERTON: Not true. Dr. Bliesner, 04:58  
6 do you have anything to add to that answer? 04:58  
7 MR. KERENSKY: If you need to hear it 04:58  
8 read back to you, Dr. Bliesner, you may ask 04:58  
9 for that. 04:58  
10 THE WITNESS: Read it back one more time, 04:58  
11 please. 04:58  
12 (Whereupon, the testimony was read back 04:59  
13 by the court reporter, as recorded above) 04:59  
14 THE WITNESS: Was the fact that nobody 04:59  
15 ever tested double-thick tablets they found in 04:59  
16 the facility. That's what I find troubling. 04:59  
17 BY MR. ANDERTON: 04:59  
18 Q. Okay. But is that more -- 04:59  
19 MR. KERENSKY: Make your objection, Mike. 04:59  
20 BY MR. ANDERTON: 04:59  
21 Q. Is that more troubling to you, 04:59  
22 Dr. Bliesner, than the fact that out of 680 04:59  
23 million tablets, in three years nobody has 04:59  
24 presented a single double-thick tablet? 04:59  
25 A. Absolutely because not testing on a 04:59

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1 product that's clearly failed and identified had 04:59

2 failed is -- it really raises eyebrows. All kinds 04:59

3 of questions come up. Why didn't they? Is 04:59

4 somebody hiding something? Have found things 04:59

5 before? Are they dumping it? These are just 04:59

6 questions that come to mind. I'm not suggesting 04:59

7 -- 04:59

8 Q. All of -- 04:59

9 A. -- all of these things. Just a whole 04:59

10 plethora of questions come into play when you 04:59

11 don't see -- it's happened several times as we 04:59

12 both recognize. 05:00

13 Q. And the way to answer those questions 05:00

14 would be to take them and dive into the 05:00

15 manufacturing and production records for that 05:00

16 product. 05:00

17 A. No, that's not true. 05:00

18 Q. Or for any other product. 05:00

19 A. That's not true. They didn't collect 05:00

20 the samples and test them. 05:00

21 Q. The way -- 05:00

22 A. In my experience -- in my experience 05:00

23 with respect to batch records, okay, personal 05:00

24 experience, recent personal experience, batch 05:00

25 records don't necessarily reflect reality. I've 05:00

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1 had a client in the last year that manufactures 05:00

2 product and doesn't even look at the batch record 05:00

3 because it isn't written where you can follow it. 05:00

4 They just go out there and wing it on the floor. 05:00

5 So just because you got a batch record doesn't 05:00

6 mean that that's gospel what's happening on the 05:00

7 floor. That's my personal experience. 05:00

8 Q. Did you throw your medicine from that 05:00

9 manufacturer away? They're not following their 05:00

10 batch records. Did you go run up to your medicine 05:00

11 cabinet and throw that away? 05:00

12 A. It's not appropriate. 05:00

13 Q. What do you mean it's not appropriate? 05:01

14 A. Because it's not a solid oral dosage for 05:01

15 me. 05:01

16 Q. Dr. Bliesner, last time you talked 05:01

17 about, you gave some testimony about conversation 05:01

18 you had with your doctor regarding this subject, 05:01

19 the subject of this litigation. And I wasn't 05:01

20 satisfied that we established whether the 05:01

21 conversation was in fact protected by a 05:01

22 physician-patient privilege. So I am going to ask 05:01

23 some questions to develop the details surrounding 05:01

24 that conversation that will tell us that. 05:01

25 A. And I'm not going to answer those 05:01

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1 questions. 05:01

2 Q. You don't have right to refuse to answer 05:01

3 that unless you -- unless it is truly privileged. 05:01

4 Do you understand that? 05:01

5 A. I believe it's truly privileged between 05:01

6 my doctor. Because I specifically asked that 05:01

7 because he asked me. 05:01

8 Q. Were you seeking medical advice when you 05:01

9 asked him these questions? 05:01

10 A. I was in for an appointment yes. 05:01

11 Q. Were you seeking medical advice when you 05:01

12 asked him questions about Digoxin? 05:01

13 A. When I asked him questions about it? I 05:02

14 didn't ask him questions. He volunteered. 05:02

15 Q. How did he come to volunteer? 05:02

16 A. I'm not comfortable talking about this. 05:02

17 Q. I'm not asking for the substance 05:02

18 A. I'm not comfortable talking about it. 05:02

19 Q. You don't have a choice. 05:02

20 MR. KERENSKY. Mike, maybe I can settle 05:02

21 this. No one is going to ask this witness to 05:02

22 tell any jury what his doctor said about 05:02

23 Digitek. I will stipulate to that right now. 05:02

24 MR. ANDERTON: Well, we're going to ask 05:02

25 this witness what his doctor told him so we 05:02

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1 know whether it formed part of the basis for 05:02  
2 his expert opinion in this case. 05:02

3 THE WITNESS: It was after the fact. I 05:02  
4 will tell you that. 05:02

5 BY MR. ANDERTON: 05:02

6 Q. You are still subject to testifying, 05:02  
7 Dr. Bliesner. 05:02

8 MR. KERENSKY: You have a right to 05:02  
9 protect your conversations between you and 05:02  
10 your doctor. And you've got two 05:02  
11 countervailing opinions from two lawyers, 05:02  
12 neither of which represent you. You got to 05:02  
13 make the call, doctor. 05:02

14 BY MR. ANDERTON: 05:03

15 Q. Dr. Bliesner, you know what you're doing 05:03  
16 here. You're setting yourself up to be brought 05:03  
17 back for another session of deposition. 05:03

18 A. So be it. I am not comfortable sharing 05:03  
19 that information with you. 05:03

20 Q. I'm allowed to ask the parameters of the 05:03  
21 conversation. I'm not asking for the substance. 05:03  
22 I'm allowed to ask the details of the 05:03  
23 conversations that surround the conversation so 05:03  
24 that I can evaluate whether I think it's a 05:03  
25 privileged communication or not. 05:03



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1 A. I'm not going to answer your 05:03

2 questions. 05:03

3 Q. I'm going to make my record. 05:03

4 Did you talk to your doctor about Digoxin. 05:03

5 Have you spoken to your doctor about Digoxin in 05:03

6 the last 12 months? 05:03

7 A. I'm not going to answer these 05:03

8 questions. 05:03

9 Q. You're refusing to answer that 05:03

10 question? 05:03

11 A. I am. 05:03

12 Q. Have you spoken to your doctor about 05:03

13 this litigation in the last 12 months? 05:03

14 A. I'm not going to answer the question. 05:03

15 Q. Have you spoken to your doctor about 05:03

16 your engagement as an expert witness in the last 05:03

17 12 months? 05:03

18 A. I'm not going to answer any 05:03

19 questions. It was within confidentiality with 05:03

20 my doctor. 05:03

21 Q. Your engagement as an expert witness? 05:03

22 A. I'm not going to answer the question. 05:04

23 Q. Have you spoken to your doctor about 05:04

24 the effects of Digoxin and its uses? 05:04

25 A. I'm not going to answer the question. 05:04

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1	Q.	Do you take Digoxin, Dr. Bliesner?	05:04
2	A.	I do not.	05:04
3	Q.	Do you take any heart medications?	05:04
4	A.	What do you mean by heart	05:04
5		medications?	05:04
6	Q.	Dr. Bliesner, do you take any	05:04
7		medications for heart conditions?	05:04
8	A.	Is blood pressure a heart condition in	05:04
9		your mind?	05:04
10	Q.	If you think it is, say yes.	05:04
11	A.	I've never really considered it a	05:04
12		heart condition. I considered it high blood	05:04
13		pressure.	05:04
14	Q.	Other than your blood pressure	05:04
15		medication, do you take any medications for	05:04
16		heart conditions?	05:04
17	A.	No.	05:04
18	Q.	Does anyone in your family take any	05:04
19		medications for heart conditions?	05:04
20	A.	No.	05:04
21		MR. ANDERTON: Off the record.	05:04
22		THE VIDEOGRAPHER: The time is	05:04
23		5:06 p.m. We're going off the record	05:04
24		briefly.	05:05
25		(Short break)	05:06

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1 THE VIDEOGRAPHER: The time is 5:07. 05:06

2 We are back on the record. 05:06

3 MR. ANDERTON: Dr. Bliesner, I have no 05:06

4 further questions at this time. 05:06

5 Unfortunately because we haven't had a 05:06

6 chance to review all the documents that you 05:06

7 produced because we have the outstanding -- 05:06

8 some outstanding issues, as much as I would 05:06

9 like to tell you that this is the final 05:06

10 session of this deposition, I can't give you 05:06

11 that guarantee. 05:06

12 THE WITNESS: I understand. 05:06

13 MR. ANDERTON: So if it is not, we will 05:06

14 in touch with counsel for the Plaintiffs to 05:06

15 make arrangements and they will be in 05:06

16 contact with you. 05:06

17 THE WITNESS: I understand. 05:06

18 MR. ANDERTON: We are going to keep 05:06

19 these binders. Phil, will you mark both of 05:06

20 these binders as the next exhibits as well? 05:06

21 And then here are the others. And they are 05:06

22 going to stay -- all of these document are 05:06

23 going to stay with Shook, Hardy, 05:06

24 Dr. Bliesner. And pursuant to agreement 05:06

25 with Mr. Kerensky, we are going to have them 05:06

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1 make copies and you're going to get back the 05:07

2 originals. And then we will get a copy. 05:07

3 THE WITNESS: Okay. 05:07

4 MR. ANDERTON: Okay. The court 05:07

5 reporter can keep a copy and then make a 05:07

6 copy. I'm sorry. The court reporter will 05:07

7 get a copy. 05:07

8 THE WITNESS: Okay. 05:07

9 MR. ANDERTON: And then we will get 05:07

10 copies as they provide us copies of the 05:07

11 transcript. 05:07

12 THE WITNESS: Okay. 05:07

13 MR. ANDERTON: Okay. Thank you very 05:07

14 much for your patience. It was a long day, 05:07

15 a long process. Thank you very much. 05:07

16 THE WITNESS: Same to you. 05:07

17 MR. ANDERTON: Mr. Kerensky. We're off 05:07

18 the record now. 05:07

19 THE VIDEOGRAPHER: The time is 5:09 p.m. 05:07

20 This concludes the videotape deposition of 05:07

21 Dr. Bliesner. We are off the record. 05:07

22 (Whereupon, Exhibits 155 and 156

23 were marked for identification)

24 (THEREUPON, the taking of the deposition  
25 was concluded at 5:09.)

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1 CERTIFICATE OF OATH

2

3 STATE OF FLORIDA

4 COUNTY OF HILLSBOROUGH

5

6 I, the undersigned authority,  
7 certify that DAVID M. BLIESNER, Ph.D.,  
8 personally appeared before me and was duly sworn  
9 by me.

10 WITNESS my hand and official  
11 seal, this 2nd day of MARCH, 2011.

12

13

14

15 \_\_\_\_\_  
PHILIP RYAN, RPR  
16 NOTARY PUBLIC - STATE OF FLORIDA  
COMMISSION # DD 988415  
17 MY COMMISSION EXPIRES: JUNE 28, 2014

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## 1 CERTIFICATE OF REPORTER

2 STATE OF FLORIDA

3 COUNTY OF HILLSBOROUGH

4 I, PHILIP RYAN, RPR, certify that I  
5 was authorized to and did stenographically  
6 report the foregoing deposition; and that the  
7 foregoing transcript is a true record of the  
8 testimony given by the witness.

9 I further certify that I am not a  
10 relative, employee, attorney, or counsel of any  
11 of the parties, nor am I a relative or employee  
12 of any of the parties' attorneys or counsel  
13 connected with the action, nor am I financially  
14 interested in the action.

15

16 DATED this 2nd day of March, 2011.

17

18

19

20

21 \_\_\_\_\_  
PHILIP RYAN, RPR

22

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25